

Exhibit 12

MAR 25 1992

INTEROFFICE CORRESPONDENCE

LOS ANGELES

TO SEE DISTRIBUTION

DATE March 25, 1992

ATTENTION

L.A. FILE

FROM R. C. MUNRO

YOUR FILE

SUBJECT

COPIES TO

CYPRUS ORE RESERVES - ARSENIC & TREMOLITE

Excerpts from Cyprus Talc Reserve Report by R.C. Munro

Geology & Environment

There are some important environmental issues related to the geology and mineralogy of the Cyprus talc deposits, particularly in Vermont.

Arsenic

Arsenic iron sulphides (arsenopyrite) are, with their alteration products, present in many of the talc-carbonate schist ore zones in the Vermont area. Total arsenic, as analyzed in the Ludlow Rainbow deposit, averages generally less than 100 ppm but with some small zones in excess of 1000 ppm. No apparent major effort is underway to regularly monitor or completely assess the total arsenic content of ores, tailing solids and wastes although the distribution of sulphides and arsenates in the talc ore system is generally understood.

In near surface weathering zones, crushed rock, stock piles and mine working areas, the arsenic sulphides (above) convert in part to the more soluble arsenates, for example, the hydrous nickel arsenate, annabergite (38% AS_2O_6). Soluble arsenic is measured in cores, ore samples, mill feed, product and tailings. Soluble arsenic content is monitored and governed under EPA/OSHA regulations.

High (e.g. +6 ppm As) soluble arsenic contents of mill feed at the West Windsor mill contribute to reduced recoveries and milling rates. At West Windsor, part of the mill recovery problem at least is being ascribed to a high fines content in the feed and to low pH of the process water, both of which contribute to increased soluble As. The problem has been under study at West Windsor since 1987 by Mill Manager, Jeff Scott, who indicated that if the arsenic content is above +6 ppm soluble As and the talc content falls below 62% talc production rates and recoveries can fall by 50%. The product specs are -3 ppm As or less at West Windsor and current material in the silos is measured at 0.73 ppm to 2.33 ppm soluble As.

To me, there also seems to be the overall risk of continuing conversion of As in sulphide to more soluble arsenates in some stockpiles, waste, and solid tailings as acid, water, air and time work on them.

Tremolite

The other serious mineralogical contaminant in the talc ores of Vermont is the fibrous variety of the amphibole minerals, tremolite and actinolite (hydrous calcium iron-magnesium silicates) which have been classified as asbestiform minerals by OSHA and EPA. OSHA was expected to de-classify non-fibrous (blocky) tremolite on February 29, but has not as yet announced their decision.

As a result, all tremolite, the fibrous varieties of all amphiboles and chrysotile asbestos in talc ores are a source of great concern to all talc producers and especially to marketers of cosmetic products.

Cyprus claims that there are no fibres in their cosmetic talc products and they work rigorously to ensure this. However, a recent paper published by Rutgers University worker, Alice Blount, suggests the presence of fibre in several cosmetic talcs, some of which might have been from Cyprus West Windsor material, which is a source of great concern to Cyprus management and potentially to their principal customer, Johnson & Johnson. Talc de Luzenac personnel are well aware of the situation and Phillipe Moreau is currently quietly working to identify the reality and the magnitude of the problem.

Vermont talcs are derived from altered serpentine - a natural host for asbestiform minerals. There is certainly visible tremolite and actinolite in specific zones of the Vermont deposits - fibrous tremolite was identified by the writer in exposures and cores at the East Argonaut and Black Bear mines. Cyprus staff report past tremolite from the Hammondsvile and Clifton deposits.

Tremolite in these deposits is encountered in the contact zones between the talc and the surrounding schist; in "grey talcs" in the vicinity of the contacts; and associated with the chlorite/amphibole waste zones within the talc ores that are locally termed "cinders". Cyprus maintains a selective mining program in Vermont that is directed toward exclusion of all of these potentially fibre-bearing zones from the ores sent to the mills, and those suspect tonnages, including the associated talc, are left in the pit walls or sent to waste piles.

Minor occurrences of amphiboles and asbestiform minerals are also attributed to confined areas of the Montana deposits. Tremolite (blocky) was encountered in a dike zone at Antler. A chlorite zone at intersecting faults at Yellowstone S40 contained some minor tremolite, and stockpiles of Beaverhead open pit fines, slated

Exhibit 13

Alice M. Blount, Ph.D.

Mineralogist

GMW

April 23, 1998

M. Raymond Hatcher
MEHAFFY & WEBER
2615 Calder Avenue
P.O. Box 16
Beaumont, Texas 77704

RECEIVED

APR 27 1998

MEHAFFY & WEBER
BEAUMONT, TEXAS

Dear Mr. Hatcher:

According to your letter of March 31, 1998, I have written and enclosed a report on the occurrence, regulation and up-to-date scientific view of asbestos, amphiboles and "intermediate" fibers. I have also enclosed copies of my 1990 and 1991 papers, one of which I am sure that you already have. The 1991 paper was written because I became aware that it was a common opinion among industrial hygienists that industrial talcs were better than pharmaceutical and cosmetic talcs because there was a regulation for the former and not for the latter. I knew that this was not the case and wanted to set the record straight.

Although my papers report an improved method for analysis, the determinations for the sample labeled *I* (Johnson & Johnson's Vermont talc) have been done by the traditional methods as well (see Table 2, page 567 in the 1990 paper). As I told you, I believe that Johnson & Johnson's Vermont talc contains trace amounts of asbestos which are well below those specified by OSHA. It should be noted that the proposed FDA regulation, which was never finalized, also specified the same 0.1% limit for amphibole asbestos as OSHA.

I may be away for short periods during the coming weeks, but I do check for messages on my work phone at the number you have been using.

Sincerely yours,



Alice M. Blount, Ph.D.

Box 3437
Rutland, VT 05701
Phone: 802-747-4857

e-mail: ambblount@together.net

J&J-0049150

JNJ 000064086

Exhibit 14

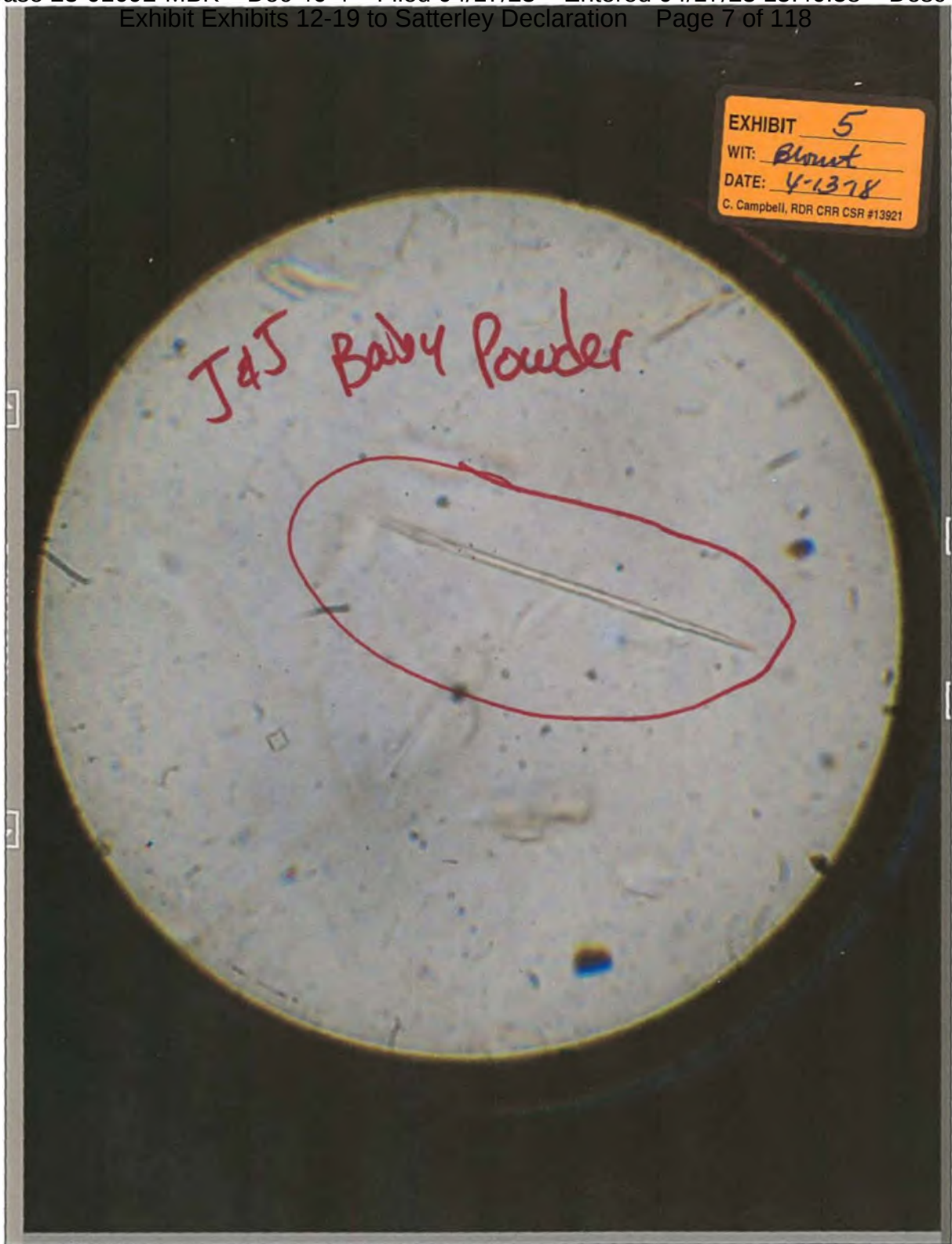


Exhibit 15



Luzenac America Technical Center • 8985 East Nichols Avenue • Englewood, CO 80112 • (303) 643-0451 • Fax: (303) 799-8926

TECHNICAL REPORT

To: **David Crouse**

From: **Julie Pier**
Analytical and Technical Support

Copy: **J. M. Godla**
S. S. Mauney
R. J. Zazenski

Analytical Project No: **A01709**
Date: **23-May-02**

Subject: **ANALYSIS OF FIBROUS MATERIAL FROM ARGONAUT**
WASTE ROCK

Request:

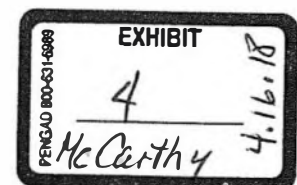
A sample of fibrous material from the waste rock on the west side of the south end of the Argonaut mine was submitted to the Technical Center for identification. The waste rock was being considered for road paving applications.

Results:

The fibrous material is tremolite.

The material was first examined by polarizing light microscopy, using the dispersion staining technique. Tremolite was preliminarily identified by this method.

Subsequent analysis by scanning electron microscopy (SEM) and transmission electron microscopy (TEM) confirmed the tremolite identification. SEM micrographs and chemical analysis by energy dispersive X-ray spectroscopy (EDS) are included in Plate 1.



Plaintiffs'
Exhibit
IC-420

**ANALYSIS OF FIBROUS MATERIAL
FROM ARGONAUT WASTE ROCK**

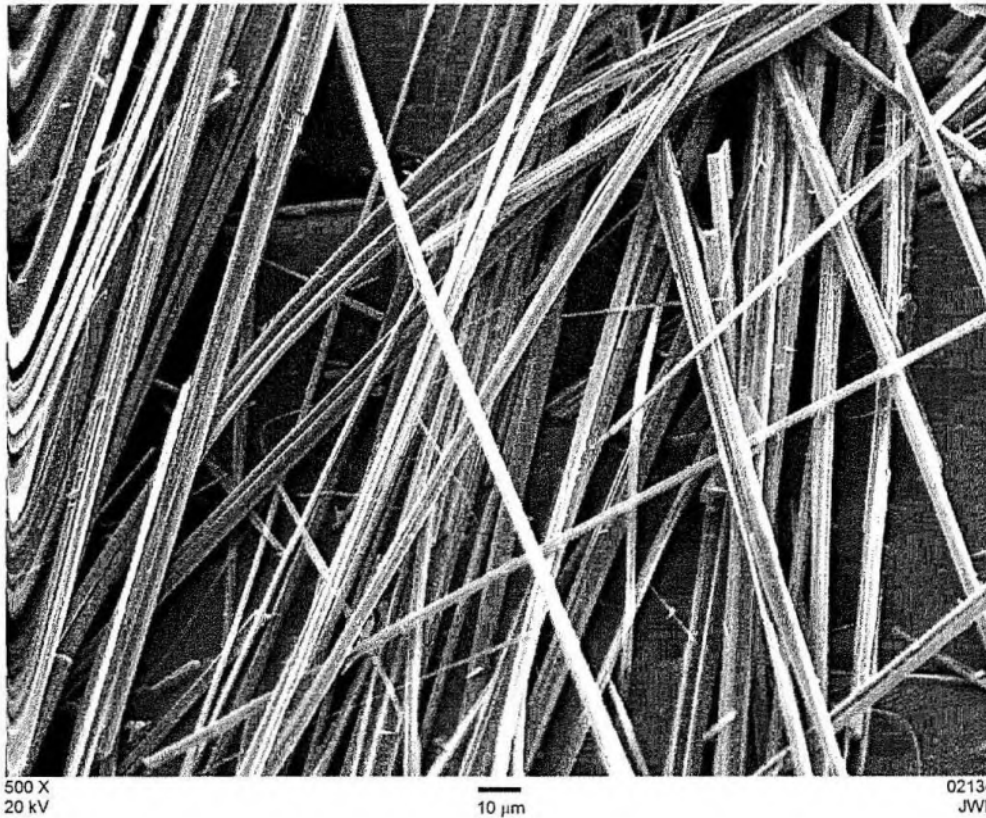
Plate 1

LUZENAC AMERICA TECHNICAL CENTER

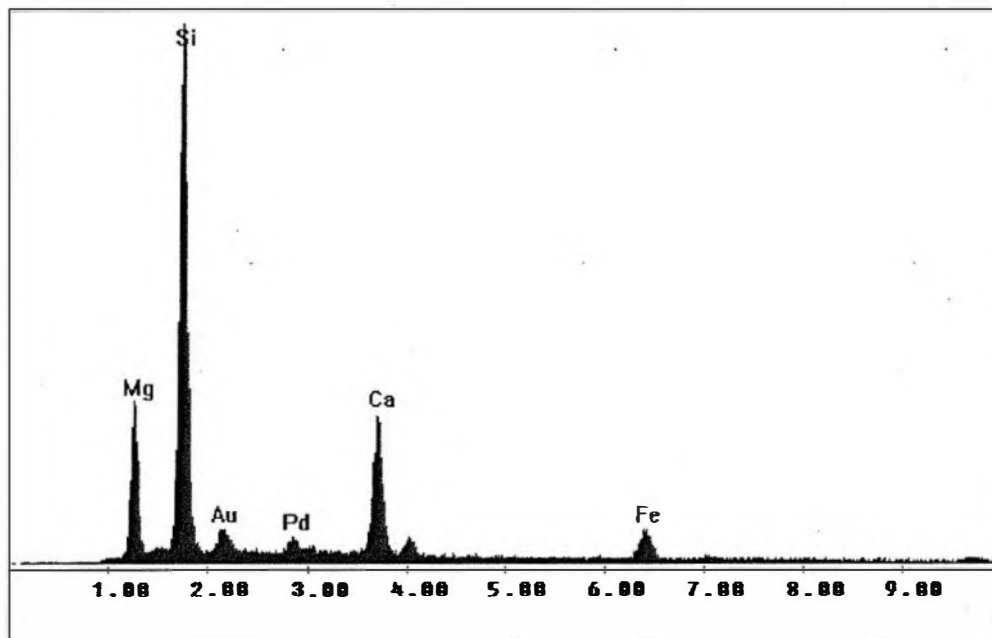
23-May-02

Project No. A01709

J.W. Pier

**SEM IMAGE**

Fibrous material found in Argonaut waste rock identified as tremolite. The material clearly has an extremely high aspect ratio.

**EDS CHEMICAL ANALYSIS**

The chemical analysis of the material, above, is consistent with tremolite.

Au and Pd peaks are from a conductive coating applied for SEM analysis.

A017091A

Exhibit 16

FEB 24 2004

5:49 PM FR J-J CORP PR

732 524 2153 TO 919089043738

P.01

facsimile transmission

To: Steve Mann - CPL

Fax: (908) 904-3738

From: Marc Monseau

Date: 2/24/2004

Corporate Communications

Re: Asbestos

Pages: 4

CC:

☐ Urgent☐ For Review☒ Please Comment☐ Please Reply☐ Please Recycle

Steve,
Last week we were contacted by a reporter at a Sacramento television station who wanted to get our reaction to a test they performed on Johnson's Baby Powder. She has since sent me the

attached cover letter and lab results, which Sarah Colamarino suggested I share with you.

Can you please review? Sarah will be calling you shortly to discuss. In the meantime, if you have any questions, please give me a call.

Best regards,

Marc Monseau

Corporate Communications

(732) 524-1130

PLAINTIFF'S
TRIAL EXHIBIT
2843

FEB 24 2004 5:49 PM FR J-J CORP PR
02/23/04 RUN 11.67

732 524 2153 TO 919089043738

P.03

KCRA TV 3

3 Television Circle Sacramento CA 95814 916 446.3333

February 23, 2004

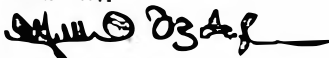
To: Mr. Mark Monseau
Johnson & JohnsonFrom: Millicent Ozdaglar
KCRA TV3

Greetings Mr. Monseau: Thank you for taking my call last week regarding KCRA TV3's Special Report on asbestos. This is a working story with no airdate. Our reporter/anchor Dave Walker is investigating the existence of harmful levels of asbestos in our community. One of the elements of the story takes a look at asbestos in household products and building materials.

One of the items tested by Hayward Laboratory was Johnson's baby powder, which tested at above normal levels for asbestos.

I am enclosing a copy of the test and results for you to look over. If you could please give me a call once you have reviewed the material, I would like to talk about the results with you.

Sincerely,



Millicent Ozdaglar
KCRA TV3 Special Projects Producer
3 Television Circle
Sacramento, Ca. 95814
(916) 325-3288

WWW.THEKCRACHANNEL.COM

FEB 25 2004 15:08

1 916 441405M

PAGE.02

19 04 04:33p

Michael Bowker

530 822 5758

P-2



Forensic Analytical

QUANTITATIVE ANALYSIS REPORT
ASBESTOS IN BULK MATERIAL
Transmission Electron Microscopy*

Michael Bowker
4069 Alice Ct
Pleasantville GA 30567

Date Collected:
Job ID: KCRS Television/Dave Walker
Site:

Page: 1 of 1
Client Number: A30388-1
Report Number: T006626
Date Received: 12/19/03
Analyst: RE
Date Analyzed: 1/5/04
Date Reported: 1/5/04

Sample Preparation: Each sample was prepared using the following quantitative techniques. Representative subsamples were weighed, ashed for 3-12 hours, at 480°C, and reweighed to determine the organic proportion. The ashed residues were ground in concentrated hydrochloric acid, dried, and reweighed to determine the acid-soluble component weight percent. The acidified residue was resuspended in a known volume of particle-free water and sonicated. Aliquots of this suspension were brought to ~20µm and filtered through 0.22µm pore-size mixed cellulose ester (MCE) membranes. After drying, these membranes were collapsed, niched, carbon-coated, and mounted on 20-mesh copper TEM grids.

Analytical Method: The analysis was performed on a Philips CM12 or Hitachi H800AB TEM at 100kV accelerating voltage. An extended low magnification analysis (~2,000x) was performed for large asbestos structures, followed by a high magnification analysis (~15,000x) for smaller asbestos structures. Asbestos structures were identified by morphology (Table 1 of 1180-1180), qualitative selected area electron diffraction (SAED), and energy dispersive x-ray analysis (EDX). In addition, the length and diameter of each asbestos structure were recorded.

Data Reduction: The asbestos concentration in each sample was calculated by first determining the volume of each asbestos structure counted, and then using magnification and density conversion factors to determine asbestos mass. The mass obtained in the high magnification analysis was then normalized to the number of grid openings analyzed and the amount volume filtered for the low magnification analysis. Since a known residue mass was passed through a known filter area, and the filter area analyzed is also known, the normalized asbestos mass in the residue can be determined and then back-calculated to the weight percent asbestos in the original sample.

| ANALYTICAL RESULTS | | | | | | |
|--------------------------------|-------------------|------------------------|-----------------------------|-------------------------|------------------|------------------------|
| Client Sample Number | Lab Sample Number | Organic Weight Percent | Acid-Soluble Weight Percent | Asbestos Weight Percent | Asbestos Type(s) | Residue Weight Percent |
| TEM 02 (Johnson's baby powder) | 20025738 | 3.6% | 6.7% | 0.20% | AN | 80.3% |
| TEM 03 (Ramon blush) | 20025739 | 28.7% | 13.1% | <0.0001% | ND | 57.2% |

Mark S. Floyd, EM Supervisor, Hayward Laboratory

* EPA Test Method 600/4-93/116, Part 2.3: Method for the Determination of Asbestos in Bulk Building Materials.

** Asbestos types: CH-chrysotile; AM-amosite; TR-tremolite; AC-actinolite; CR-crocidolite; AN-anthophyllite; ND-none detected.

3777 Olsen Road, Suite 400, Hayward, California 94545-7761 • Telephone: 510/887-8070 • Fax: 510/887-4218

FEB 23 2004 15:00

1 916 4414750

PAGE 03

Sample Preparation: Each sample was prepared using wet methods. The samples were ground in a mortar, ashed for >12 hours, at 400°C, and reweighed to determine the organic proportion. The ashed residues were ground in concentrated hydrochloric acid, diluted, and reweighed to determine the acid-soluble component weight percent. The acidified residue was resuspended in a known volume of deionized water and sonicated. Aliquots of this suspension were brought to >200m and filtered through 0.22um pore-size mixed cellulose ester (MCE) membranes. After de-drying, these membranes were collapsed, etched, carbon-coated, and mounted on 200-mesh copper TEM grids.

Analytical Method: The analysis was performed on a Philips CM12 or Hitachi H6000A TEM at 100kV accelerating voltage. An extended low magnification analysis (~2,300x) was performed for large asbestos structures, followed by a high magnification analysis (~19,000x) for smaller asbestos structures. Asbestos structures were identified by morphology (Variable Level II definitions), qualitative selected area electron diffraction (SAED), and energy dispersive x-ray analysis (EDX). In addition, the length and diameter of each asbestos structure were recorded.

Data Reduction: The asbestos concentration in each sample was calculated by first determining the volume of each asbestos structure counted, and then using magnification and density conversion factors to determine asbestos mass. The mass detected in the high magnification analysis was then normalized to the number of grid openings analyzed and the aliquot volume filtered for the low magnification analysis. Since a known residue mass was passed through a known filter area, and the filter area analyzed is also known, the normalized asbestos mass in the residue can be determined and then back-calculated to the weight percent asbestos in the original sample.

| ANALYTICAL RESULTS | | | | | | |
|--------------------------------|-------------------|------------------------|-----------------------------|-------------------------|--------------------|------------------------|
| Client Sample Number | Lab Sample Number | Organic Weight Percent | Acid-Soluble Weight Percent | Asbestos Weight Percent | Asbestos Type(s)** | Residue Weight Percent |
| TEM-02 (Johnson's baby powder) | 20025738 | 3.8% | 6.7% | 0.20% | AN | 69.3% |
| TEM 03 (Rayon Blush) | 20025739 | 29.7% | 13.1% | <0.0001% | ND | 57.2% |

Mark S. Floyd, EM Supervisor, Hayward Laboratory

* EPA Test Method 600/4-93-010, Part 2.6: Method for the Determination of Asbestos in Bulk Building Materials.

** Asbestos types: CH=chrysotile; AM=amosite; TR=trichite; AC=actinolite; CR=crocidolite; AN=anthophyllite; ND=none detected.

3777 Depot Road Suite 400, Hayward, California 94545-7761 • Telephone: 510/887-8828 • Fax: 510/887-4710

FEB 23 2004 15:09

1 016 4414850

PAGE.04

** TOTAL PAGE.05 **

Exhibit 17

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 1 of 56

AMA Analytical Services, Inc.
Focused On Results.

CERTIFICATE OF ANALYSIS

Chain of Custody: 308006

Client: US Food & Drug Administration
Address: Office of Cosmetics & Colors
4300 River Road
College Park, MD 20740
Attention: John Gasper

Job Name: Task 3 - Analysis of Official Samples
Job Location: 4th Group - 15 Samples
Job Number: CLIN 1- Task 3
PO Number: HHSF223201810337P

Date Submitted: 7/24/2019
Date Analyzed: 8/20/2019-9/18/2019
Report Date: 10/3/2019
Date Sampled: Not Provided
Person Submitting: Goran Periz
Revised: 10/11/2019 (Revision #2)

SUMMARY OF ANALYSIS

| AMA Sample ID | Client Sample ID | TEM LOD Using ASTM D5756 Mass Calculation | TEM LOQ Using ASTM D5756 Mass Calculation | % Tremolite by TEM Using ASTM D5756 Mass Calculation | % Chrysotile by TEM Using ASTM D5756 Mass Calculation | % Total Tremolite & Chrysotile by TEM Using ASTM D5756 Mass Calculation | % Asbestos by PLM | % Organics | % Acid Soluble | % Other | Comments |
|---------------|------------------|--|--|---|--|--|-------------------|------------|----------------|---------|---|
| 308006-6 | D-58 | 0.00000169% | 0.00000675% | ND | ND | ND | ND | 0.3% | 6.7% | 93.1% | Organics = 0.3%; Acid Soluble = 7.1%; Other = 92.6% Gravimetric Loss from PLM Prep: |
| 308006-6A | D-58 | 0.00000133% | 0.00001485% | ND | < 0.00001% | < 0.00001% | ND | 0.2% | 19.5% | 80.2% | |
| 308006-68 | D-58 | 0.00000135% | 0.00000540% | ND | 0.00002% | 0.00002% | ND | 0.2% | 11.2% | 88.6% | Other = 94.2% |

LOD = Limit of Detection

LOQ = Limit of Quantification

ND = Not Detected

PLM = Polarized Light Microscopy

TEM = Transmission Electron Microscopy

Analytical Method(s): PLM by Modified NY ELAP 198.6
TEM by Modified NY ELAP 198.4/ASTM D5756

Analyst(s): PLM
TEM

Technical Director: Andreas Saldivar

All results are to be considered preliminary and subject to change unless signed by the Technical Director or Deputy

This report applies only to the sample, or samples, investigated and is not necessarily indicative of the quality or condition of apparently identical or similar products. As a mutual protection to clients, the public, and these Laboratories, this report is submitted and accepted for the exclusive use of the client to whom it is addressed and upon the condition that it is not to be used, in whole or in part, in any advertising or publicity matter nor shall it be reproduced, except in full, without prior written authorization from us. Sample types, locations, and collection protocols are based upon the information provided by the persons submitting them and, unless collected by personnel of these Laboratories, we expressly disclaim any knowledge and liability for the accuracy and completeness of this information. Residual sample material will be discarded in accordance with the appropriate regulatory guidelines, unless otherwise requested by the client. NVLAP accreditation applies only to polarized light microscopy of bulk samples and transmission electron microscopy of AMBI-Air samples. This report must not be used to claim, and does not imply product certification, approval, or endorsement by NY ELAP, AMA, NVLAP, NIST, or any agency of the Federal Government. All rights reserved. AMA Analytical Services, Inc.

Record Changes Report

Client: US Food & Drug Administration

Client Code: FDA

Chain of Custody: 308006

| Date | Description |
|------------|--|
| 10/11/2019 | 308006 6, 6A, 6B/D 58: 1) added initials & dates to all strike throughs and additions to gravimetric bench sheets. 2) revised handwritten TEM bench sheet for 6B to break up the single cluster found on Grid B, GO I8 into its 3 component fibers 3) changed the word "fiber" to "structure" on p. 4 of Case Narrative under LoQ discussion for 6A & 6B & updated the basis of LoQ calculation for 6B. 4) changed the word "fiber" to "structure" in reference to chrysotile on p.4 of Case Narrative under the TEM Discussion and Interpretation of Analytical Findings. 5) Updated the picture for 308006 6B Chrysotile Structure 1 on p. 6 of Case Narrative. 6) revised reported LoQ, concentration of chrysotile & total cocentration for aliquot 6B based off of 4 structures (original concentration was based off of 2 structures). 7) added gravimetric loss data for PLM preparations to comments section of the certificate of analysis. |
| 10/08/2019 | 308006 6, 6A, 6B/D58: 1) The Special Instructions section of the login sheet was revised to include the FDA's cancellation of a request for analyzing a 4th aliquot of D 58 (308006 6C). 2) The preparation date was added to pages 2 & 3 of the TEM gravimetric bench sheet and to page 2 of the PLM gravimetric bench sheet; an explanation for the date written in the right hand margin of both sets of bench sheets was added to them; added missing weights for 308006 16 and 308006 17. 3) The handwritten TEM Bench Sheet for 308006 6A was revised to explain that the 2nd Chrysotile structure was identified based upon tubular morphology; also the structure number count for the 2nd listed stricture was corrected to read "#2" |

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 3 of 56

AMA Analytical Services, Inc.

Focused on Results www.amalab.com
AIIIA-LAP (#100470) NYI-LAP (#101143-0) NY ELAP (10920)
4475 Forbes Blvd. • Lanham, MD 20706
(301) 459-2640 • (800) 346-0961 • 459-2643

CHAIN OF CUSTODY

(Please Refer To This
Number For Inquiries)

308006

Information:

1. Client Name:
2. Address:
3. Address:
4. Address 3:
5. Phone #:

4. Contact Person:
- 5.

Cell:
Cell:

Reporting Info (Results provided as soon as technically feasible). If no TAT/Reporting Info is provided, AMA will assign defaults of 5-Day and email/fax to contacts on file.

AFTER HOURS (must be pre-scheduled)

- ☐ 4 Hours ☐ Late Night
☐ Immediate Date Due:
☐ 24 Hour Time Due:

Comments:

Asbestos Analysis

- *P M Air Please Indicate Filter Type:
☐ NIOSH 7400 (QTY)
☐ Fiberglass (QTY)

- TEM Air* - Please Indicate Filter Type:
☐ AHFRA (QTY)
☐ IOSH 7402 (QTY)

- P 1 Bulk (specify) (QTY)
☐ EPA 600 - Visual (QTY) ☐ Pos Stop
☐ Point Count
☐ Y State Friable 198.1 (QTY)
☐ Gray Reduction ELAP 198.6 (QTY)
Other (specify) (QTY)

MISC

- ☐ Asbestos Soil PLM (Qual) PLM (Quant) PLM/TEM (Qual) PLM/TEM (Quant)
*It is recommended that blank samples be submitted with all air and soil samples

- ☐ 4 Hours
☐ Same Day
Next Day
☐ 2 Day

NORMAL BUSINESS HOURS

- ☐ 3 Day
☒ 5 Day +
Date Due:
☐ Results Required By Noon

REPORT TO:

- ☐ Email:
☐ Email 2:
☐ Verbal:

TEM Bulk

ELAP 198.4/ Hatfield
State PLM/TEM

TEM

- ☐ Qual. (pres/abs) Vacuum/Dust (QTY)
Quant. (s/area) Vacuum D5755-95 (QTY)
☐ Quant. (s/area) Dust D6180-99 (QTY)

TEM Water

- Qual. (pres/abs) (QTY)
☐ ELAP 198.2/EPA 100.2 (QTY)

Analysis

- ☐ Pb Paint Chip (QTY)
☐ *Pb Dust Wipe (wipe type) (QTY)
☐ Pb Soil/Solid (QTY)
☐ Pb TULP (QTY)
Drinking Water ☐ Pb (QTY) ☐ Cu (QTY) ☐ As (QTY)
☐ Waste Water ☐ Pb (QTY) ☐ Cu (QTY) ☐ As (QTY)
☐ Pb Furnace (Media) (QTY)

Fungal Analysis

Collection Apparatus for Spore Traps/Air Samples:

Collection Media

- ☐ *Spore Trap (QTY) ☐ Surface Vacuum Dust (QTY)
☐ *Surface (QTY)
☐ *Surface Ta (QTY)
☐ Other (Specify) (QTY)

MATRIX

COMMENTS /
SPECIAL INSTRUCTIONS

CLIENT ID # SAMPLE 1 FOR IDATION DATE/ VOL (L)

SAMPLE LOCATION/ ID

ANALYSIS

Print Name

Date

Time

ATTACHMENT B: CFSAN OFFICE OF COSMETICS AND COLORS CHAIN OF
CUSTODY FORM

CF AN
Office of Cosmetics and Colors
CHAIN OF CUSTODY FORM

Case/Lab

Submitter: ___Goran Periz

Assignment No./ Contract No.: HHSF223201810337P

Date Sealed: 7/23/2019

Sample Type: 15 samples D-53 to D67

4

6

9

10

11

12

13

14

Chain of

| Item # | Date | Received by (Print | Received by | Comments/Location |
|--------|-----------|-----------------------|-------------|-------------------|
| 1-15 | 7/24/2019 | | | |

Page 1 of 2 pages (See back)

CHAIN OF CUSTODY FORM (Continued)

Final Authorization for Disposal

Item(s) #: _____ on this document is/are no longer needed as evidence and is/are authorized for disposal by (check appropriate disposal method)

☐ Return to Submitter ☐ Destruction

Name of Authorizing Official: _____

Date: _____

Signature: _____

Witness to Destruction of Evidence

Item(s) #: _____ on this document were destroyed by (Name)
in my presence on (date)

Name of Witness to destruction: _____

Signature: _____

Date: _____

Adapted from: Technical Working Group on Biological Evidence Preservation. *The Biological Evidence Preservation Handbook: Best Practices for Evidence Handlers*. U.S. Department of Commerce, National Institute of Standards and Technology. 2013.

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 6 of 56

Release to Lawful Owner

Item(s) this document was/were released by Evidence Custodian
ID#: to

Zip Code:

Telephone Number: ()

Under penalty of law, I certify that I am the lawful owner above

Signature:

Date:

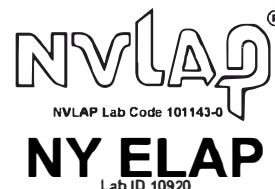
Copy of Government-issued photo identification is attached. ☐ Yes ☐ No

This is to be retained as a permanent record by the Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors.

Page 2 of 2 pages (See front)

Adapted from: Technical Working Group on Biological Evidence Preservation. *The Biological Evidence Preservation Handbook: Best Practices for Evidence Handlers*. U.S. Department of Commerce, National Institute of Standards and Technology. 2013.

AMA Analytical Services, Inc.
Focused On Results.



Case Narrative

Client Name: FDA Office of Cosmetics & Colors
PO Number: HHSF223201810337P
Job Name/Location: Task 3 – Analysis of Official Samples (4th Group – 15 Samples)
AMA COC Number: 308006-6, 6A, 6B/D-58
Contact: John Gasper
Phone: (240) 402-1133
Email:
Date Received: July 24, 2019

| AMA Sample No. | Client Sample No. | Sample Description | Analytical Method |
|----------------|-------------------|---|-------------------------------------|
| 308006-6 | D-58 | Slightly clumpy, white powder with a matte appearance | Mod. PLM ELAP 198.6 /TEM ELAP 198.4 |
| 308006-6A | D-58 | | Mod. PLM ELAP 198.6 /TEM ELAP 198.4 |
| 308006-6B | D-58 | | Mod. PLM ELAP 198.6 /TEM ELAP 198.4 |

Requested Analyses: PLM and TEM Analysis for asbestos fibers conducted by Modified NY ELAP Method 198.6 and Modified NY ELAP Method 198.4

Sample Receipt:

The samples were received by AMA Analytical Services, Inc. on July 24, 2019 at 1058 via in-person drop-off by FDA representative, Goran Periz. The set consisted of 15 (fifteen) samples submitted in ~2oz, glass jars sealed with scotch tape. Conditions were checked upon receipt and all sample containers were intact. Most jars were filled approximately ½ to ¾ full. The sample set was processed on AMA Chain-of-Custody (COC) number 308006. This COC number served as the internal laboratory job number for tracking purposes. The samples were entered into the AMA laboratory database on August 12, 2019 at 1151 by [REDACTED]. The samples were logged in for analysis in triplicate and each sample aliquot was assigned a unique laboratory identification number as shown in the table above. After the sample login, the set was transferred to AMA's lock-box for storage.

The following pictures document the condition of each sample upon receipt at AMA:

Asbestos • Lead • Mold • Nano

4475 Forbes Boulevard • Lanham, MD 20706 • (301) 459-2640/(800) 346-0961 • Fax (301) 459-2643 • www.amalab.com

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*Re: FDA Office of Cosmetics & Colors
COC 308006-6, 6A, 6B/D58, Revised 10/11/2019 (Revision #2)*

308006-6 6A

D58

Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

Sample Preparation

Samples were prepared for PLM and TEM bulk analysis by (b) (6) on August 13, 2019 through September 5, 2019. Sample preparation consisted of the following steps:

- 1) Label and weigh two 8mL glass vials for each sample in the set – one vial for the PLM preparation and one vial for the TEM preparation.
- 2) Weigh out 0.1 to 0.8 grams of material and place in corresponding 8mL glass vial. Record weight.
- 3) Burn samples at 480° C for at least 12 hours.
- 4) Record Post-Ash Weight.
- 5) Treat ashed sample with concentrated hydrochloric acid.
- 6) Filter acid reduced material onto a pre-weighed 47mm 0.4um PolyCarbonate filter.
- 7) Place filter into drying oven for 30 minutes and then record Post-Acid Reduced weight.
- 8) Make four PLM slide preparations from the PLM residual ash for each sample in 1.550 dispersion oil. Make additional preparations in 1.605, 1.625, 1.680 and 1.700 dispersion oil as necessary for particle identification.
- 9) Weigh a portion of the residue from the TEM residual ash and place it into the corresponding pre-weighed 100ml jar.
- 10) Fill the 100ml jar with deionized water
- 11) Sonicate the jars for approximate 5-minutes.
- 12) Filter 0.2ml to 1ml of the solution onto a 47mm 0.22um MCE filter.
- 13) Dry the filter for 10 minutes then collapse, carbon coat, and place on a 3 TEM grids.

PLM Analysis

Analysis was performed in accordance with NY ELAP 198.6 protocols. The analysis was conducted using an Olympus BH-2 polarized light microscope (PLM) equipped with a dispersion staining objective. All four slide preparations for each aliquot were examined. 400-point count was performed for those samples on which asbestos was observed. If no asbestos was detected on any of the slides, the percentage of fibrous components was determined by visual estimation. The results of this analysis are detailed below in the *Discussion and Interpretation of Analytical Findings* section for each individual sample.

TEM Analysis

Analysis was performed in accordance with modified NY ELAP Method 198.4 protocols. The analysis was performed using a JEOL JEM-100CX II transmission electron microscope (TEM), equipped with a Thermo Fisher Quest Energy Dispersive X-Ray Analyzer (EDXA), at magnifications of 19,000x. Two grids for each aliquot were examined. Twenty (20) grid openings were examined per sample.

Modifications to the NY ELAP 198.4 Method were:

- 1) The residue was not placed in alcohol and prepared using the quick drop method. To obtain a more uniform preparation, the residue was placed in a jar and filled with 100ml of deionized water. The jar was sonicated, and a portion of the solution was filtered onto a 47mm 0.22um MCE filter.
- 2) The tremolite and chrysotile were not visually estimated. The length and width of the observed particles were measured, and the mass of each amphibole particle was calculated using the ASTM D5756 method.
- 3) All particles identified as tremolite were included with the counts/concentrations, regardless of size and aspect ratio.

The results of this analysis are detailed below in the *Discussion and Interpretation of Analytical Findings* section for each individual sample.

Calculations

ASTM D5756 Mass

$$M = \pi/4 L * W^2 * D * 10^{-12}$$

M = mass

L = length



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W = width

D = density

Percent Calculation

$$\frac{EFA(mm^2) * 100ml * MA(g) * RW(g)}{VF(ml) * IW(g) * AA(mm^2) * RJ(g)}$$

The calculated value is then multiplied by 100 to convert it to percent.

EFA – Effective filter area

MA – Mass of asbestos

RW – Weight of residue

VF – Volume filtered

IW – Initial weight of the sample

AA – Area analyzed

RJ – Weight of residue placed into the jar

Limit of Detection and Quantification

We used the mass of a 0.5 x 0.04-micron tremolite or chrysotile fiber, depending on what was found in each sample, as the basis for our calculations. Limit of detection was defined as 1 fiber and limit of quantification was defined as 4 fibers.

Some aliquots of sample D58 contained very small amounts of asbestos that were either at or below our 4-fiber limit of quantification. For these samples we defined our limit of quantification as follows:

308006-6A: mass of the two observed chrysotile structures plus the mass of two chrysotile fibers measuring 0.5 x 0.04 microns

308006-6B: mass of 4 chrysotile fibers measuring 0.5 x 0.04-micron

Discussion and Interpretation of Analytical Findings:

308006-6, 6A, 6B Client Sample D-58

PLM

All three aliquots of sample D-58 were analyzed by (b) (6) on September 13, 2019. No asbestos or non-asbestos amphibole variants were detected the samples. The results were calculated using the equations detailed in the calculations section.

308006-6 NAD

308006-6A NAD

308006-6B NAD

TEM

Sample 6 was analyzed by (b) (6) on September 3, 2019. Samples 6A and 6B were analyzed by (b) (6) on September 7, 2019. The primary particle observed was talc along with a few talc fibers, talc ribbons and mica particles. Two Chrysotile structures were detected on the aliquot for 6A and four chrysotile structures were detected on the aliquot for 6B. The results were calculated using the equations detailed in the calculations section.

308006-6 NAD

308006-6A <0.00002%

308006-6B 0.00002%

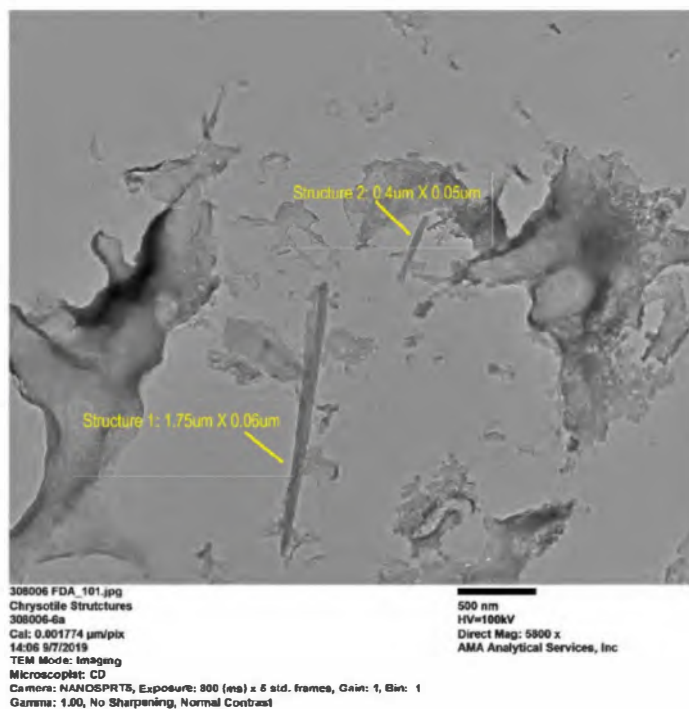
Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The unidentified peaks in chemistry spectra are copper, zinc, and carbon. Those peaks are from the TEM specimen holder and specimen grid.



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Sample 308006-6A, Chrysotile Structures



Diffraction Pattern from Chrysotile Structure 1 pictured above



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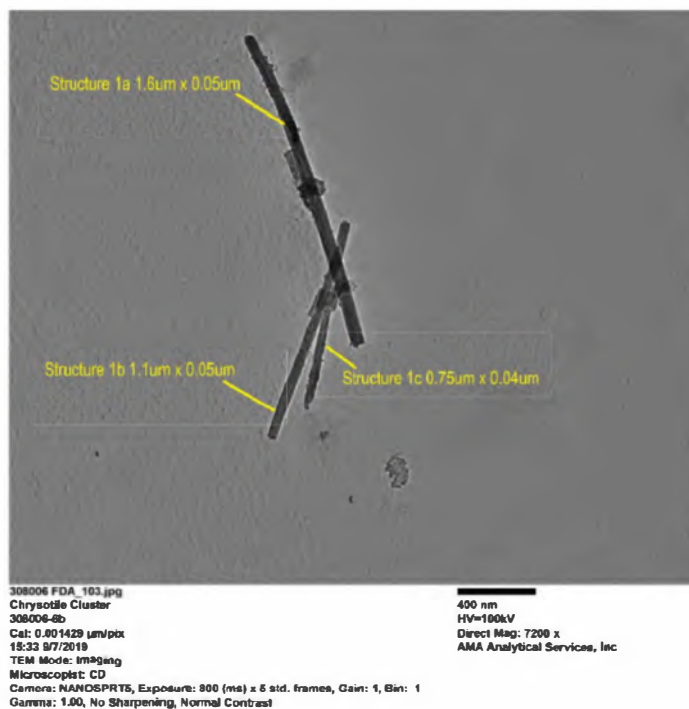
JNJTALC001284327

Prudencio Pltfs' Ex. 1571 pg11

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Re: FDA Office of Cosmetics & Colors
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Sample 308006-6B, Chrysotile Structure 1



Diffraction Pattern from Chrysotile Structure pictured above



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Prudencio Pltfs' Ex. 1571 pg12

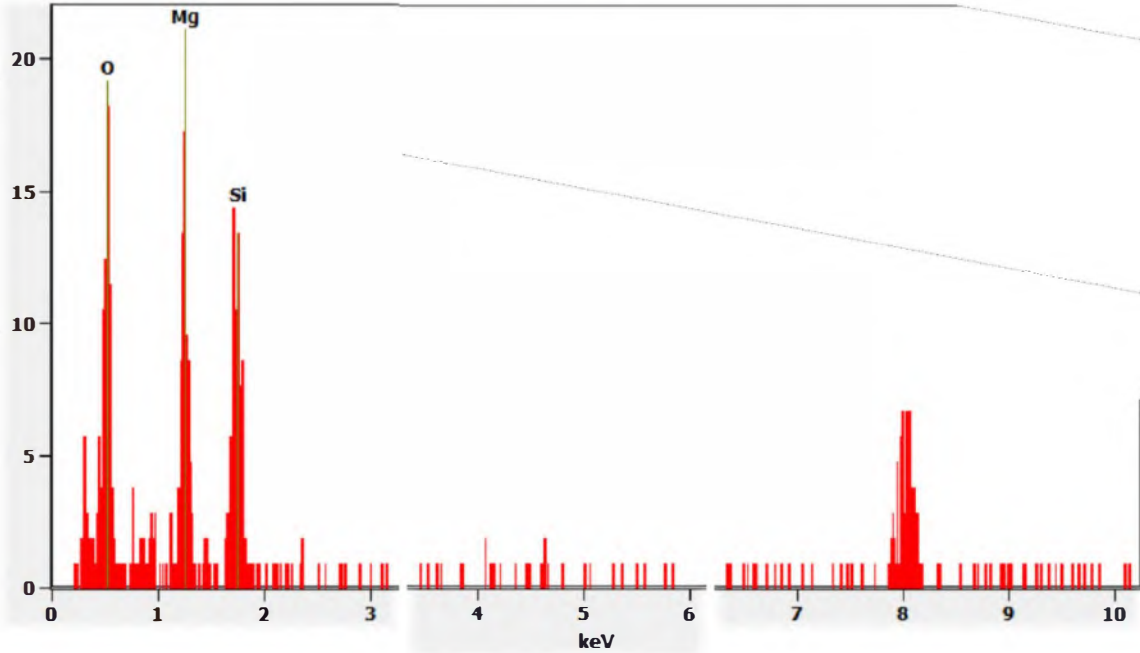
Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

Chemistry from Chrysotile Structure pictured above

Full scale counts: 22

308006-6B(1)



308006-6B, Chrysotile Structure 2

Note: a copy of this page, with
image un-redacted is attached
at the end of this document



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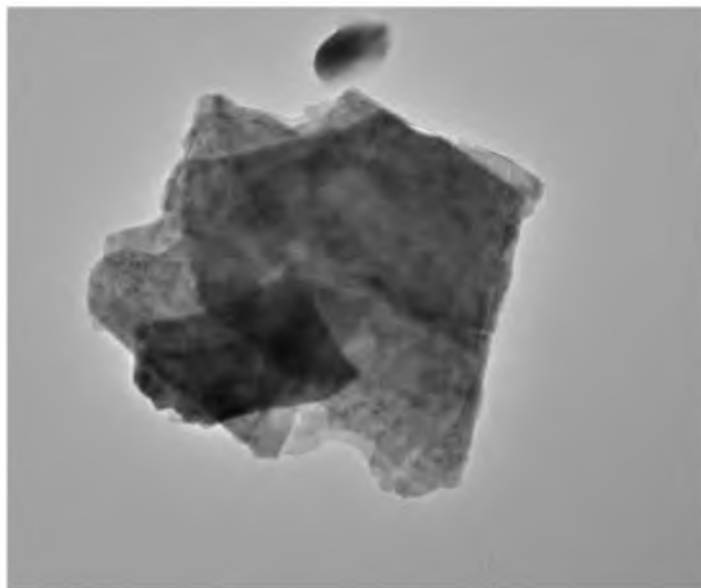
Diffraction Pattern from Chrysotile Structure pictured above



308006 FDA_104.jpg
Chrysotile Dif
308006-6
16:03 9/7/2019
TEM Mode: Diffraction
Microscopist: CD
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 sld. frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

100 r1(A)
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc.

308006-6, Talc Particle



308006 FDA_082.jpg
Talc Particle
Cal: 0.001774 $\mu\text{m}/\text{pix}$
17:18 9/3/2019
TEM Mode: Imaging
Microscopist: MG
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

500 nm
HV=100kV
Direct Mag: 6800 x
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Prudencio Pltfs' Ex. 1571 pg14

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Hexagonal Diffraction Pattern from Talc Particle pictured above

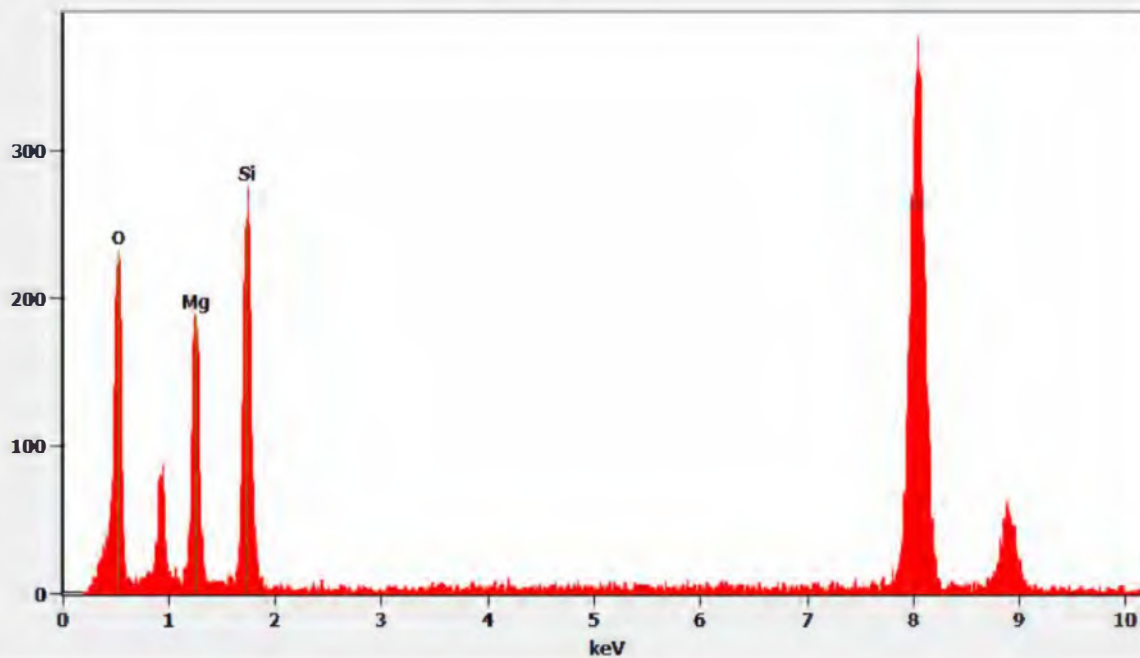


308006 FDA_053.jpg
Talc Particle
17:19 9/3/2019
TEM Mode: Diffraction
Microscopist: MG
Camera: NANOSPRTS, Exposure: 900 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast
100 e-/Å²
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Chemistry from Talc Particle pictured above

Full scale counts: 377

308006-6(1)



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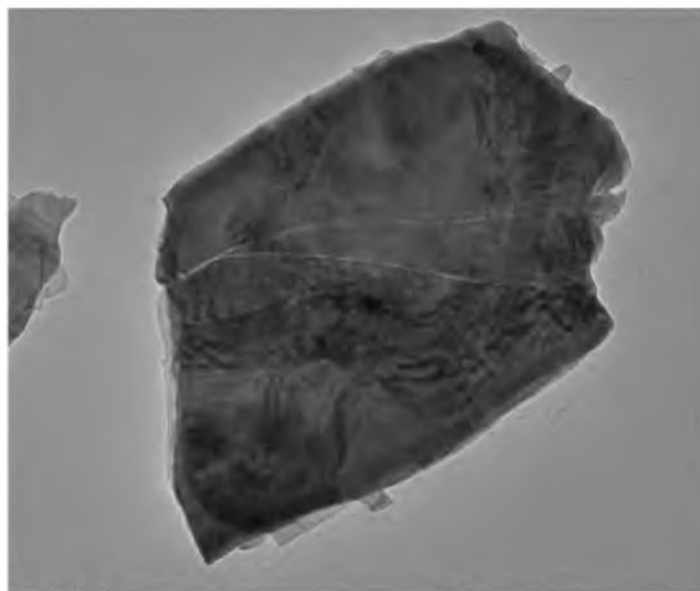
Prudencio Pltfs' Ex. 1571 pg15

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Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

306008-6, Mica Particle



308006 FDA_054.jpg

Mica Particle

Cal: 0.001429 $\mu\text{m}/\text{pix}$

17:21 9/3/2019

TEM Mode: Imaging

Microscopist: MG

Camera: NANOSPRT6, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1

Gamma: 1.00, No Sharpening, Normal Contrast

400 nm

HV=100kV

Direct Mag: 7200 x

AMA Analytical Services, Inc.

Diffraction Pattern from Mica Particle pictured above



308006 FDA_056.jpg

Mica Particle

17:22 9/3/2019

TEM Mode: Diffraction

Microscopist: MG

Camera: NANOSPRT6, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1

Gamma: 1.00, No Sharpening, Normal Contrast

100 f1/A1

HV=100kV

Cam Len: 0.2200 m

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Prudencio Pltfs' Ex. 1571 pg16

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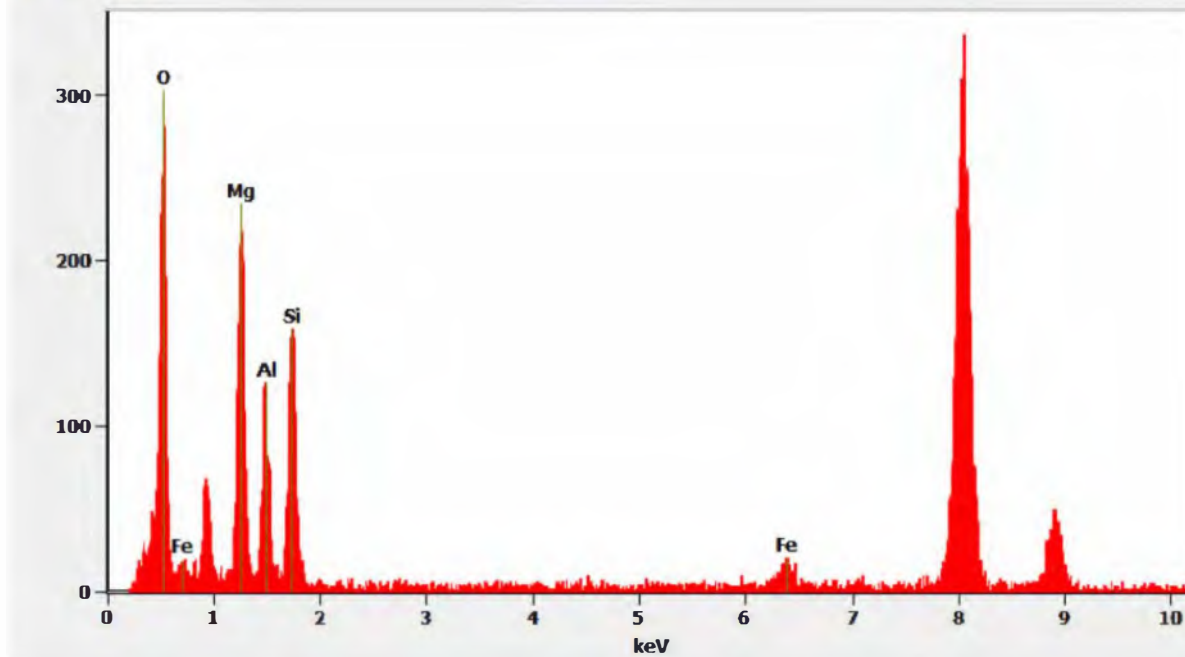
Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

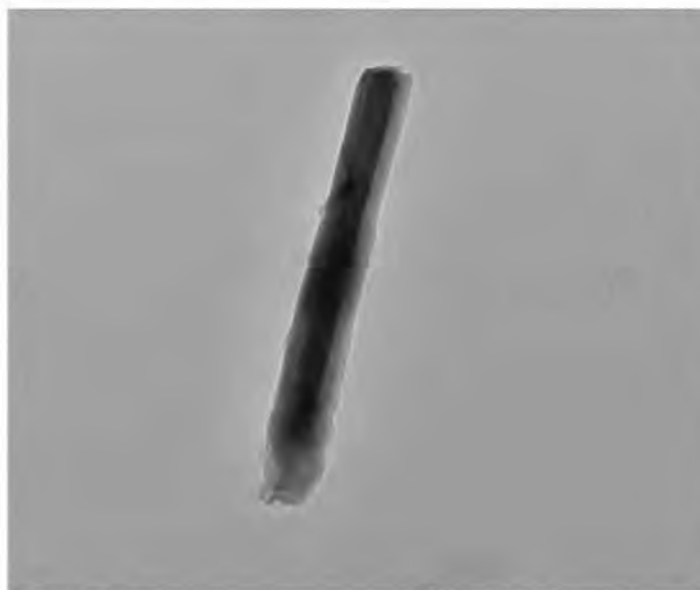
Chemistry from Mica Particle pictured above

Full scale counts: 337

308006-6(2)



308006-6, Talc Fiber



308006 FDA_057.jpg
Talc Fiber
Cal: 0.734821 nm/px
17:27 5/3/2019
TEM Mode: Imaging
Microscopist: MG
Camera: NANOSPRTS, Exposure: 800 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

200 nm
HV=100kV
Direct Mag: 14000 x
AMA Analytical Services, Inc.



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JNJTALC001284333

Prudencio Pltfs' Ex. 1571 pg17

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Re: FDA Office of Cosmetics & Colors
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Diffraction Pattern from Talc Fiber pictured above

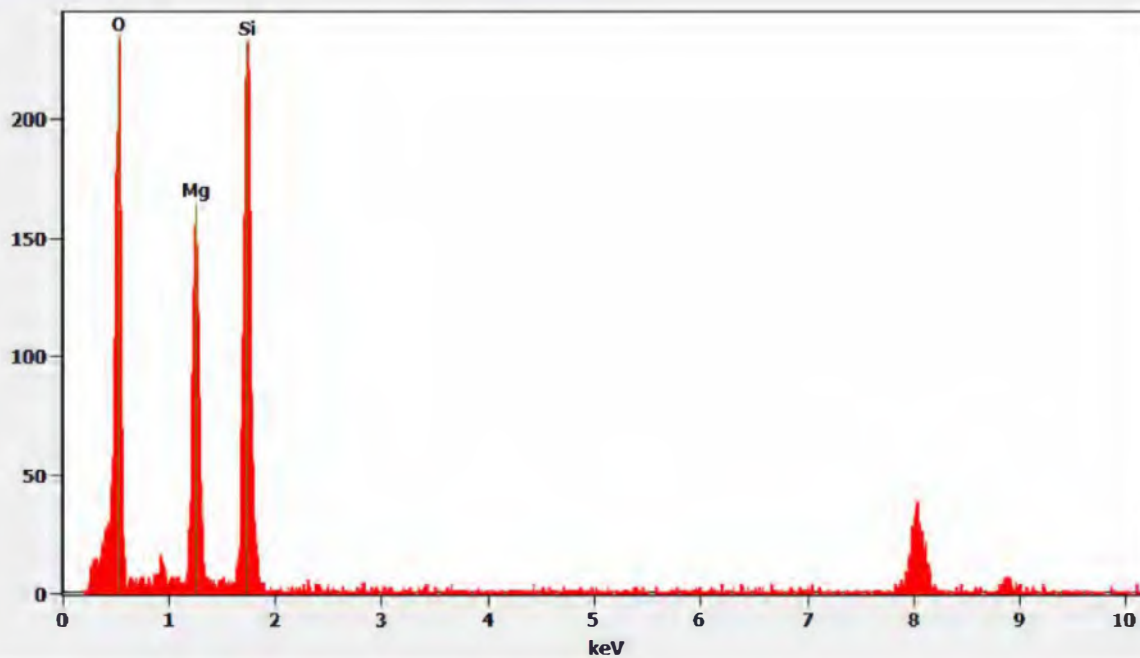


308006 FDA_058.jpg
Talc Fiber
17:28 9/3/2019
TEM Mode: Diffraction
Microscopist: MG
Camera: NANOSPRTS, Exposure: 900 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast
100 e-/Å²
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Chemistry from Talc Fiber pictured above

Full scale counts: 235

308006-6(3)



AMA Analytical Services, Inc.

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Prudencio Pltfs' Ex. 1571 pg18

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Re: FDA Office of Cosmetics & Colors
COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

308006-6, Talc Ribbon



Diffraction Pattern from Talc Ribbon pictured above



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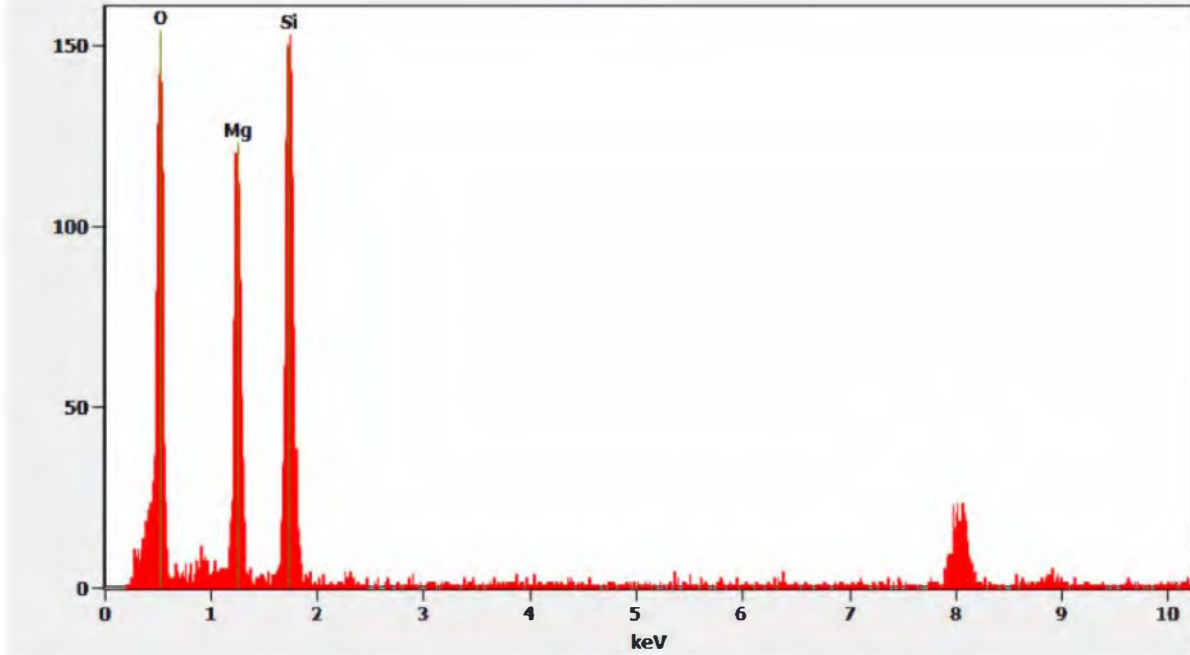
Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

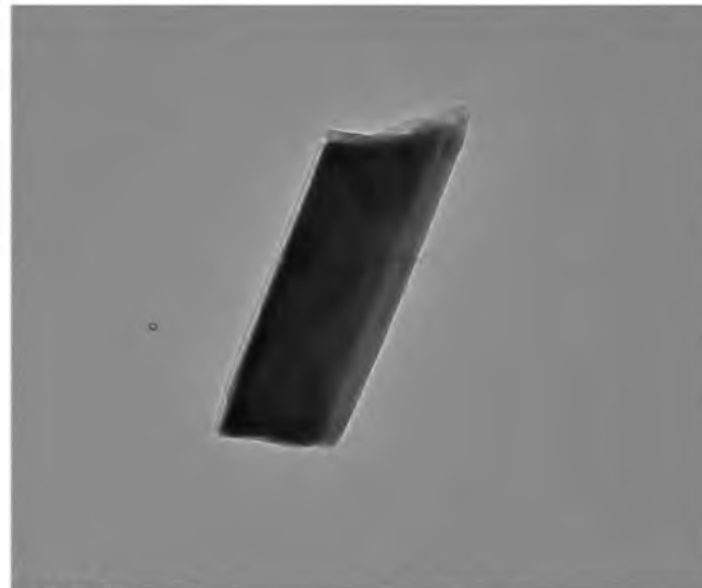
Chemistry from Talc Ribbon pictured above

Full scale counts: 155

308006-6(4)



308006-6, Talc Fiber



308006 FDA_061.jpg

Talc Fiber

Cal: 0.001629 um/plx

17:50 9/3/2019

TEM Mode: Imaging

Microscopist: MG

Camera: NANOSPRTS, Exposure: 800 (ms) x 8 drift frames, Gain: 1, Bin: 1

Gamma: 1.00, No Sharpening, Normal Contrast

200 nm

100kV

Direct Mag: 10000 x

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JNJTALC001284336

Prudencio Pltfs' Ex. 1571 pg20

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Re: FDA Office of Cosmetics & Colors
COC 308006-6, 6A,6B/D58, Revised 10/11/2019 (Revision #2)

Diffraction Pattern from Talc Fiber pictured above

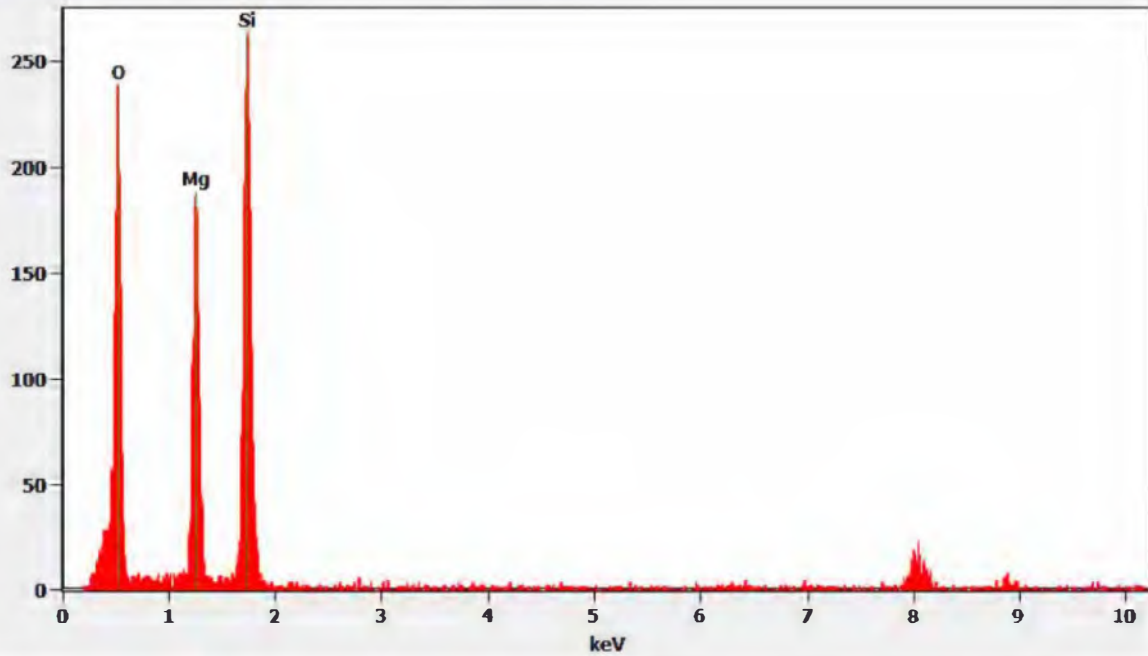


308006 FDA_062.jpg
Talc Fiber
17:51 9/3/2019
TEM Mode: Diffraction
Microscopist: MG
Camera: NANOSPRTS, Exposure: 900 (ms) x 5 drift frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast
100 (1/Å)
HV=100kV
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Chemistry from Talc Fiber pictured above

Full scale counts: 264

308006-6(5)



AMA Analytical Services, Inc.

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JNJTALC001284337

Prudencio Pltfs' Ex. 1571 pg21

Re: FDA Office of Cosmetics & Colors

COC 308006-6, 6A, 6B/D58, Revised 10/11/2019 (Revision #2)

QC Discussion:

During preparation, three blank control samples and one reference control sample were prepared. These samples were prepared alongside the customer samples. The blank samples were prepared using Sigma-Aldrich Talc Powder, <10 micron, and was analyzed by [REDACTED] on September 18, 2019. No asbestos was detected on the blank samples. The reference sample was made from the same Sigma-Aldrich talc powder spiked with 10% Chrysotile. The reference sample was analyzed by [REDACTED] on September 18, 2019 and found to be within acceptable limits. Additionally, filter blanks were prepared with each batch of carbon coated filters. Filter blank number EB-54155 was associated with the carbon coating for samples 308006-6, 6A, 6B/D-58. No asbestos was detected on the filter blank sample.

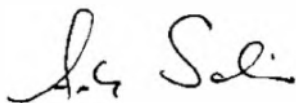
Our laboratory information management system (LIMS) randomly selected samples 308006-2/D-54 and 308006-15/D-67 for additional replicate QC analysis. Separate preparations were made for PLM and TEM analysis. The replicate QC analysis was performed by [REDACTED] on September 13, 2019, 2019 for PLM analysis and by [REDACTED] on September 18, 2019 for TEM analysis. The QC results matched the original analysis.

Attachments:

The following items are attached to this case narrative for your reference:

- 1) Sample Log-In Sheet
- 2) Daily PLM Scope Calibration Log
- 3) Refractive Index Oil Calibration Log
- 4) Daily TEM Scope Calibration Log
- 5) QC Results Summary
- 6) Replicate & Duplicate QC Chart for (b) (6) for samples analyzed between 1/1/2019 and 9/18/2019
- 7) Replicate & Duplicate QC Chart for (b) (6) for samples analyzed between 1/1/2019 and 9/18/2019
- 8) Replicate & Duplicate QC Chart for (b) (6) for samples analyzed between 1/1/2018 and 9/18/2019
- 9) Raw Data Sheets
 - a. Gravimetric Data
 - b. Filtration Worksheets
 - c. PLM Analysis
 - d. TEM Analysis
 - e. QC Samples

I certify that all information contained in this report pertaining to laboratory events, procedures, and protocols is true and accurately describes the handling of this project by AMA Analytical Services, Inc. and its personnel.



Andreas Saldivar
Laboratory Director

10/11/2019

Date



AMA Analytical Services, Inc.

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Login Sheet

Client: US Food & Drug Administration
Date Submitted: 07/24/2019
Due Date: 09/13/2019 5:00 pm

Job Name: Task 3 - Analysis of Official Samples
Job Location: 4 h Group - 15 Samples
Job Number: CLIN 0001

Chain of Custody: 308006
PO Number: SF225201810337P

AMA Sample Number

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Client Sample Number

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Analysis Type(s) and Sample Type(s)

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[illegible]

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[illegible]

Special Instructions:

Use FDA Protocols. Samples are in Asbestos Sample Lock Box (See (b) (6) for Key). ALL PLM & TEM Analysts: Please record the date & amount of time spent analyzing each sample in the comments section of the bench sheet. Please save all pictures, graphs, etc. to L:\Case Narratives\FDA Project\308006

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9/30/2019 by (b) : Client requested that we analyze a 4th aliquot for sample 308006 6/D58; this was added as 308006 6C

10/1/2019 by (b) : Client requested that we cancel their request to analyze 308006 6C, Preparation was mostly complete by the time we received the
cancellation notice, but no analysis was performed.

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Daily Calibrations for PLM Scope # 2

Date: 9/12/19

Analyst Initials: (b) (6)

Cleaning:

Oculars ☒ Objectives ☒ Field Lens ☒ Mechanical Stage ☒ Main Body ☒

Alignment:

- ☒ Kohler Illumination (or as close to it as scope allows)
- ☒ Polarizer & Analyzer at 90 degrees to one another
- ☒ Polarizer & Analyzer aligned with reticule cross hairs
- ☒ Axis of rotation of stage centered in field of view
- ☒ Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1.680 Amosite:

440 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

Daily Calibrations for PLM Scope # 2

Date: 9/13/19

Analyst Initials: (b) (6)

Cleaning:

Oculars ☒ Objectives ☒ Field Lens ☒ Mechanical Stage ☒ Main Body ☒

Alignment:

- ☒ Kohler Illumination (or as close to it as scope allows)
- ☒ Polarizer & Analyzer at 90 degrees to one another
- ☒ Polarizer & Analyzer aligned with reticule cross hairs
- ☒ Axis of rotation of stage centered in field of view
- ☒ Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1.680 Amosite:

440 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

Daily Calibrations for PLM Scope # 2

Date: 9/16/19

Analyst Initials: (b) (6)

Cleaning:

Oculars ☒ Objectives ☒ Field Lens ☒ Mechanical Stage ☒ Main Body ☒

Alignment:

- ☒ Kohler Illumination (or as close to it as scope allows)
- ☒ Polarizer & Analyzer at 90 degrees to one another
- ☒ Polarizer & Analyzer aligned with reticule cross hairs
- ☒ Axis of rotation of stage centered in field of view
- ☒ Central stop of the D.S. objective aligned with condenser aperture

Refractive Index Colors of Permanent 1.680 Amosite:

440 Parallel wavelength 660 Perpendicular wavelength

Comments/other procedures performed:

REFRACTIVE INDEX OIL CALIBRATION

[illegible]

Revision 2, February 19, 2007

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DAILY TEM CALIBRATION LOG

Every analyst should confirm alignment prior to analyzing samples.
X-ray analyzer must be calibrated prior to each day's use.
Dewar for X-ray detector is to be filled each Tuesday and Friday.

Note: Please enter code letters in Type Column.

Type of Analysis: Routine Analysis A
Quality Control QC
Training T
Research R
Other (Explain) O

| TRANSMISSION ELECTRON MICROSCOPE | | | | | | | X-RAY ANALYZER | |
|----------------------------------|---------|----------------------------|-------------------------|-----|--------------------|------|-------------------------|------------------------|
| DATE | NAME | SYSTEM/ ALIGN. CHECK | ACTUAL "BEAM TIME" USED | | TOTAL # SAMPLES | TYPE | EDXA CAL. (AL/CU) | DEWAR LN2 (INIT) |
| | | | ON | OFF | | | | |
| 9/3/19 | (b) (6) | OK | | | | | | |
| 9/4/19 | (b) (6) | OK | Filament Changed | | | | | |
| 9/5/19 | (b) (6) | OK | | | | | cuok | |
| 9/6/19 | (b) (6) | OK | 0900 | | 12 | A | | |
| 9/7/19 | (b) (6) | OK | 1230 | | 17 | A | | |
| 9/8/19 | (b) (6) | OK | | | | | | |
| 9/9/19 | (b) (6) | OK | | | | | | |
| 9/10/19 | (b) (6) | OK | | | | | | |
| 9/11/19 | (b) (6) | OK | | | | | | |
| 9/12/19 | (b) (6) | OK | | | | | | |

Version 2-1:9/90

Revision O, Kuroki Oct. 2004

AS
cuok

Chain Of Custody #308006

+ Add CoC

General Samples Documents **QC Results**

QC Samples

| Date Analyzed | Sample Number | Original PLM Analyst | Original PLM Result | PLM QC Result | PLM QC Analyst | PLM R Value | Original TEM Analyst | Original TEM Result | TEM QC Result | TEM QC Analyst | TEM R Value | Comments |
|---------------|---------------|----------------------|---------------------|---------------|----------------|-------------|----------------------|---------------------|---------------|----------------|-------------|-------------------|
| 09/09/2019 | 308006-16RQC | (b) (6) | 0.00 | | SW | 0.00 | MG | 0.00 | 0.00 | CD | 0.00 | Analysis 9/18/19 |
| 09/09/2019 | 308006-17RQC | (b) (6) | 0.00 | | SW | 0.00 | MG | 0.00 | 0.00 | CD | 0.00 | Analysis: 9/18/19 |

Reference Samples

| Sample Number | Title # | Analyst | Asbestos Type | Percent Asbestos | Result | Created Date | Comments |
|---------------|--------------|---------|---------------|------------------|--------|--------------|----------|
| Talc Ref | Talc Ref 10% | (b) (6) | Chrysotile | 10.00 | Pass | 09/18/2019 | |

Blanks

| Blank Number | Date | Analyst | Asbestos Percentage | Asbestos Type | Comments |
|--------------|------------|---------|---------------------|---------------|----------|
| NB19-646 | 09/18/2019 | (b) (6) | 0.0 | | |
| NB19-645 | 09/18/2019 | (b) (6) | 0.0 | | |
| NB19-647 | 09/18/2019 | (b) (6) | 0.0 | | |

PLM Error(s)

No Results

TEM NOB Error(s)

No Results

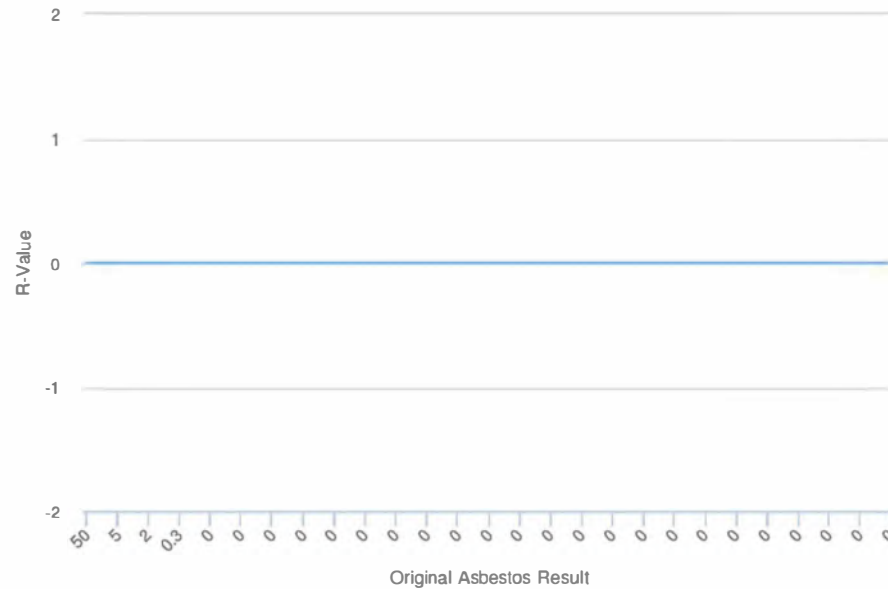
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PLM QC Chart

QC Type: Duplicate

Analyst: (b) (6)

Dates Analyzed: 01/01/2019 - 09/18/2019



$R = [\text{Original Result}] - [\text{QC Result}] / [\text{Average}]$

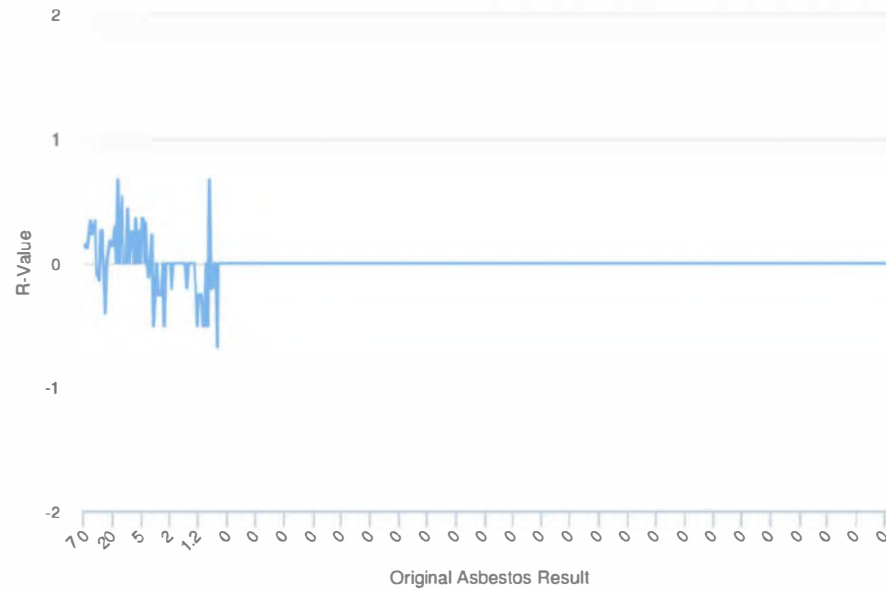
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PLM QC Chart

QC Type: Replicate

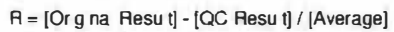
Analyst: (b) (6)

Dates Analyzed: 01/01/2019 - 09/18/2019



$R = [\text{Original Result}] - [\text{QC Result}] / [\text{Average}]$

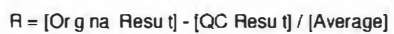
Dates Analyzed: 01/01/2019 - 09/18/2019



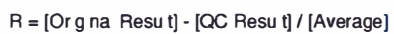
Dates Analyzed: 01/01/2019 - 09/18/2019



Dates Analyzed: 01/01/2019 - 09/18/2019



Dates Analyzed: 01/01/2019 - 09/18/2019



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AMA Analytical Services, Inc.
Focused On Results.

Gravimetric Reduction and Filtration Bench Sheet for Modified ELAP 198.4

Page 1 of 3

TEM Preparations

COC #: 308006

Date: 8/13/2019 & 9/30/19

Client: USFDA

Prep By: (b) (6)

Filter Type: 47 mm, 0.22 µm, MCF EFA: 1047 mm²

Filtered By: (b) (6) Lot #: R9CA03145 Date: see margin

| Gravimetric Reduction Weights | | | | | | Filtration Weights | | Filtration Volumes | | | | |
|-------------------------------|------------------|---------------------------|---------------------------------------|---------------------------------|---|------------------------------|--|------------------------|-------------------------|---|--|---|
| AMA Sample ID | Mass (g) Vial | Mass (g) Vial & Sample | Mass (g) Post Ash Vial & Sample | Mass (g) Filter & Petri Dish | Mass (g) Post Acid Wash Filter & Petri Dish | Mass (g) 100ml Jar w/ Lid | Mass (g) 100ml Jar w/ Lid & Sample Residue | Initial Volume (mL) | Volume Filtered (mL) | Serial Dilution Initial Volume (mL) <small>(If left blank, no serial dilution performed)</small> | Serial Dilution Volume Filtered (mL) <small>(If left blank, no serial dilution performed)</small> | Serial Dilution Final Volume (mL) <small>(If left blank, no serial dilution performed)</small> |
| (b) (4) | | | | | | | | | | | | |
| 308006-6 | 7.2520 | 7.6844 | 7.6833 | 6.0877 | 6.4902 | 19.6991 | 19.8935 | 100 | .2 | | | |
| -6A | 7.1474 | 7.6335 | 7.6324 | 6.0891 | 6.4791 | 19.7148 | 19.8949 | 100 | .2 | | | |
| -6B | 7.1687 | 7.6634 | 7.6622 | 6.0903 | 6.5285 | 19.8223 | 20.0189 | 100 | .2 | | | |
| (b) (4) | | | | | | | | | | | | |

8/19/2019

9/30/2019

Revised: 3, issued April 2019, CPH

JNJALC001284353



AMA Analytical Services, Inc.
Focused On Results.

Gravimetric Reduction and Filtration Bench Sheet for Modified ELAP 198.4

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TEM Preparations

COC #: 308006

Client: USFDA

Date:

Prep By:

Filter Type: 47 mm, 0.22 μ m, MCE EFA: 1047 mm²

Filtered By:

Lot M

_____; Date: _____

Date

ate: see margin

18/01/2014

Gravimetric Reduction Weights

Filtration Weights

Filtration Volumes

[illegible]

8/30/2019

9/5/2019

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AMA Analytical Services, Inc.
Focused On Results.

Gravimetric Reduction and Filtration Bench Sheet for Modified ELAP 198.4

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COC #: 308006

Client: USFDA

TEM Preparations

Date: 8/13/19 + 9/13/19

Prep By: (b) (6)

Filter Type: 47 mm, 0.22 µm, MCE EFA: 1047 mm²

Filtered By: (b) (6)

Lot #: R9CA03145

Date: 8/13/19

Gravimetric Reduction Weights

Filtration Weights

Filtration Volumes

| AMA Sample ID | Mass (g) Vial | Mass (g) Vial & Sample | Mass (g) Post Ash Vial & Sample | Mass (g) Filter & Petri Dish | Mass (g) Post Acid Wash Filter & Petri Dish | Mass (g) 100mL Jar w/ Lid | Mass (g) 100mL Jar w/ Lid & Sample Residue | Initial Volume (mL) | Volume Filtered (mL) | Serial Dilution Initial Volume (mL) (if left blank, no serial dilution performed) | Serial Dilution Volume Filtered (mL) (if left blank, no serial dilution performed) | Serial Dilution Final Volume (mL) (if left blank, no serial dilution performed) |
|------------------|------------------|---------------------------|---------------------------------------|---------------------------------|---|------------------------------|--|------------------------|-------------------------|---|--|---|
| (b) (4) | | | | | | | | | | | | |
| NB19-645 | 7.2023 | 7.5055 | 7.5051 | 6.0260 | 6.2879 | 19.6999 | 19.8381 | 100 | .2 | | | |
| NB19-646 | 7.1965 | 7.4457 | 7.4452 | 6.0241 | 6.2595 | 19.8538 | 19.9748 | 100 | .2 | | | |
| NB19-647 | 7.1488 | 7.5222 | 7.5218 | 6.0210 | 6.3629 | 19.8468 | 20.0132 | 100 | .2 | | | |
| RB | | | | | | | | | 10% | | | |
| <u>also/a</u> | | | | | | | | | | | | |
| <u>308006-66</u> | 7.1367 | 7.5613 | 7.5601 | 6.1753 | 6.5876 | 20.8765 | 21.0656 | 100 | .2 | | | |
| NB19-649 | 7.2313 | 7.5347 | 7.5335 | 6.2610 | 6.5578 | 19.8215 | 19.9581 | 100 | .2 | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |

9/5/2019

10/2/19

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AMA Analytical Services, Inc.
Focused On Results.

Gravimetric Reduction Bench Sheet

Modified ELAP 198.6

PLM Preparations

Page 1 of 2

COC #: 308006

Date: 8/13/2019

Client: USFDA

Prep By: (b) (6)

| AMA Sample ID | Mass (g) Vial | Mass (g) Vial & Sample | Mass (g) Post Ash Vial & Sample | Mass (g) Filter & Petri Dish | Mass (g) Post Acid Wash Filter & Petri Dish |
|---------------|------------------|---------------------------|---------------------------------------|---------------------------------|---|
| (b) (4) | | | | | |
| 308006-16 | 7.1829 | 7.6946 | 7.6932 | 6.2233 | 6.6973 |
| -6A | 7.1097 | 7.5536 | 7.5526 | 6.1705 | 6.5757 |
| -6B | 7.2309 | 7.7182 | 7.7167 | 6.2312 | 6.6900 |
| (b) (4) | | | | | |

8/19/2019 = Test Filtration Date
- 8/19/2019

8/30/2019 = Test Filtration Date
- 8/30/2019



AMA Analytical Services, Inc.
Focused On Results.

Gravimetric Reduction Bench Sheet

Modified ELAP 198.6

PLM Preparations

Page 2 of 2

COC #: 308006

Date: 8/13/2019

Client: USFDA

Prep By: (b) (6)

| AMA Sample ID | Mass (g) Vial | Mass (g) Vial & Sample | Mass (g) Post Ash Vial & Sample | Mass (g) Filter & Petri Dish | Mass (g) Post Acid Wash Filter & Petri Dish |
|---------------|------------------|---------------------------|---------------------------------------|---------------------------------|---|
| (b) (4) | | | | | |
| NB19- 645 | 7.2023 | 7.5055 | 7.5051 | 6.0260 | 6.2879 |
| NB19- 646 | 7.1965 | 7.4457 | 7.4452 | 6.0241 | 6.2595 |
| NB19- 647 | 7.1488 | 7.5222 | 7.5218 | 6.0210 | 6.3629 |
| BB | | | | | 10 % |

Revision 1, Issued April 2019, UNH

JNJTALC001284357

Prudencio Pltfs' Ex. 1571 pg41

JNJTALC001284358

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Edit Sample #308006-6 (D-58)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight

Vial Weight 7.252
Vial + Sample Weight 7.6944
Initial Sample Weight 0.442

Post Ash Weight

Vial + Ashed Sample Weight 7.6835
Ashed Sample Weight 0.431

Post Acid Treatment

Filter Tare 6.0877
Gross Filter Weight 6.4902
Weight Residue 0.402

Visual Estimations

Estimated Asbestos PLM 0.0
Estimated Asbestos TEM 0.0

Final Asbestos Percents

Percent Asbestos PLM NAD
Percent Asbestos TEM NAD

Final Non-Asbestos %

Percent Organics 0.254
Percent Acid Soluble 6.66
Percent Other 93.085

Sample Type

Whole

Material Type

Sample Color

Grid Box

A19-433

Row and Slots

Tab

Microscope #

1

Working Mag. High (X)
15

Working Mag. Low (X)

Accelerating Voltage (KV)
100

Sample was not analyzed

Structure Crystallographic and Photographic Data

| Structure # | SAED | Element | Mag. # | Camera Length / Mag. | Ident. |
|-------------|------|------------------------|--------|----------------------|--------|
| 5 | Hex | Mg, Si, Talc Fiber | | 10 | |
| 4 | Neg | Mg, Si, Talc Ribbon | | 5.8 | |
| 3 | Hex | Mg, Si, Talc Fiber | | 14 | |
| 2 | Hex | Mg, Al, Si, Fe, Mica F | | 7.2 | |
| 1 | Hex | Mg, Si, Talc Particle | | 5.8 | |

Add Row

Grid #1 Estimated Asbestos

0.0

Grid #2 Estimated Asbestos

0.0

Estimated Asbestos %

0.0%

Analyst Comments

Orientation - 250, 115
Grid A analyzed 9/3/19, Grid B analyzed 9/4/19,
Analytical time = 1.5 hrs

Report Comments

Error(s) Found During Review

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
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Edit Sample #308006-6A (D-58)

General: PUMP EAP 10686 N38 T500 Bulk Upgrade

Initial Sample Weight

Net Weight: 7.147g
 Net + Sample Weight: 7.800g
 Initial Sample Weight: 0.653g

Post Ash Weight

Net + Ashed Sample Weight: 7.802g
 Ashed Sample Weight: 0.655g

Post Acid Treatment

Filter Type: 0.8um
 Gross Filter Weight: 3.470g
 Weight Residue: 0.090g

Visual Estimation

Estimated Asbestos PLM: 3.8

Final Asbestos Percent

Percent Asbestos PLM: 96%

Final Non-Asbestos %

Percent Organic: 0.338
 Percent Acid Soluble: 19.543
 Percent Other: 80.119

Material Type: Powder
Color: White
Heterogeneity: Homogeneous
Sample Type: Whole
Texture: Powdery

☐ Sample was not analyzed
☐ Fibrous
☒ Increasing Negative Option
☐ Standard Point Count
☒ 400 Point Count

Asbestos Percent

Chrysotile Percent:
 Amosite Percent:
 Crocidolite Percent:
 Other Asbestos Percent:

Non-Asbestos %

Mineral Wool Percent:
 Fiberglass:
 Organic:
 Synthetic:
 Other:

Non-Fibrous Percent

Particulate: 100.0
 Other Non-Fibrous:

Microscopic Comments

Temperature (°C): 25.0
 Microscope #: 2

| Sample # | Color | Heterogeneity | Net Wt | Net + Ash | Net + Acid | Net + Filter | Net + Filter + Ash | Net + Filter + Ash + Acid | Net + Filter + Ash + Acid + Filter | Net + Filter + Ash + Acid + Filter + Ash | Net + Filter + Ash + Acid + Filter + Ash + Acid | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid + Filter | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid | Net + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid + Filter + Ash + Acid + Filter |
|----------|-------|---------------|--------|-----------|------------|--------------|--------------------|---------------------------|------------------------------------|--|---|--|--|---|--|--|---|--|
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

Asbestos Points

Chrysotile Points: Pending ☐ Trace Detected but no points
 Amosite Points: Pending ☐ Trace Detected but no points
 Crocidolite Points: Pending ☐ Trace Detected but no points
 Other Asbestos Points: Pending ☐ Trace Detected but no points
 Total Asbestos Points: Pending 96% ☐ < 0.38%

Non-Asbestos Fiber Percentages

Mineral Wool + Fiberglass Contained:
 Organic:
 Synthetic:
 Other:

Non-Fibrous Percentages

Particulate: 100.0
 Other Non-Fibrous:

☐ Recommend TEM
☐ Recommend Matrix Reduction

Microscopic Comments

Report Comments

External Record Dating Review

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
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Edit Sample #308006-6A (D-58)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight

Vial Weight 7.1474
Vial + Sample Weight 7.6335
Initial Sample Weight 0.486

Post Ash Weight

Vial + Ashed Sample Weight 7.6324
Ashed Sample Weight 0.485

Post Acid Treatment

Filter Tare 6.0891
Gross Filter Weight 6.4791
Weight Residue 0.390

Visual Estimations

Estimated Asbestos PLM 0.0
Estimated Asbestos TEM 0.01

Final Asbestos Percents

Percent Asbestos PLM NAD
Percent Asbestos TEM 0.906

Final Non-Asbestos %

Percent Organics 0.226
Percent Acid Soluble 19.543
Percent Other 80.222

Sample Type

Whole

Material Type

Sample Color

Grid Box

a19-433

Row and Slots

2ab

Microscope #

1

Working Mag. High (X)

15

Working Mag. Low (X)

Accelerating Voltage (KV)

100

Sample was not analyzed

Structure Crystallographic and Photographic Data

| Structure # | SAED | Elements | Mag. # | Camera Length / Mag. | Ident. |
|-------------|----------------------|----------|--------|----------------------|------------|
| 5 | hex | | | | |
| 4 | uto (0.4x0.05) Grid | uo | 101 | 5.8 | Chrysotile |
| 3 | pos (1.75x0.06) Grid | Si Mg | 100 | 0.22/5.8 | Chrysotile |
| 2 | neg | | | | |
| 1 | hex | | | | |

Add Row

Grid #1 Estimated Asbestos

0.01

Grid #2 Estimated Asbestos

0.01

Estimated Asbestos %

0.01%

Analyst Comments

Analysis: 9/7/19, time = 1hr 10 mins
F Orientation: 285.40

Report Comments

Error(s) Found During Review



AMA Analytical Services, Inc.
Focused On Results.

Fiber Count Sheet for Transmission Electron Microscopy

Page 1 of 1

Date: 09/07/19 Client ID: D-58 Filter Size/Type/Porosity 47mm MCE 0.22 µm
 Client: FDA COC #: 308006 AMA ID #: 308006-6A
 Analyst: (b) (6) Working Mag: 15 K Accel Voltage: 100 kV Orientation of Letter F: F, F
 Grid Box #: A19-433 Grid Acceptable: (Y) N Volume Filtered: 0.2 mL
 Signed: [Signature] Row #: 2 Grid: A/B Grid Openings to Observe: 20
 Method: Mod. NY ELAP 198.4 (FDA Procedures)

[illegible]

Legend: NSD = No Structures Detected UTO = Unable to Obtain

| | | | |
|--|-----------|---|-----------|
| | = 1st Grd | X | = 2nd Grd |
|--|-----------|---|-----------|

Mineral Type: chrysotile = 2 Total
Mineral Type: _____ = _____
Mineral Type: _____ = _____
Mineral Type: _____ = _____

Total # of Grid Openings Observed: 20 = 0.280 mm² # of Structures Counted: 2

Mean Grid Opening Area: 0.0 140 mm²

Notes: Structure #2 determined

EM Serial #: S/N 156120-35

to be chrysotile asbestos
based on morphology (fibrous)

Chemistry was 0 to due to the size of the fibres surrounding particulate.

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Edit Sample #308006-SR (D-56)

General: PLUP-ELAP-106924-008 TESP Bulk Upgrade

Initial Sample Weight:
Net Weight: 7.9897
Net + Sample Weight: 7.9896
Initial Sample Weight: 0.494

Post Acid Weight:
Net + Ashed Sample Weight: 7.9922
Ashed Sample Weight: 0.494

Post Acid Treatment:
Filter Type: 3.8800
Gross Filter Weight: 3.6205
Weight Residue: 0.438

Visual Estimation:
Estimated Asbestos PLM: 3.8

Final Asbestos Percent:
Percent Asbestos PLM: 96.6

Final Non-Asbestos %:
Percent Organic: 0.243
Percent Acid Soluble: 11.778
Percent Other: 88.07

Material Type: Powder
Color: White
Heterogeneity: Homogeneous
Sample Type: Whole
Texture: Powdery

☐ Sample was not analyzed
☐ Rhinoceros
☒ Assuming Negative Option
☐ Standard Point Count
☐ 400 Point Count

Asbestos Percent:
Chrysotile Percent:
Amosite Percent:
Crocidolite Percent:
Other Asbestos Percent:

Non-Asbestos %:
Mineral Wool Percent:
Fiberglass:
Organic:
Synthetic:
Other:

Microscopic Comments:

Temperature (°C): 25.0
Microscope: 2

| Sample Type | Color | Composition | Est. Age | Est. 1 | Est. 2 | Est. 3 | Est. 4 | Est. 5 | Est. 6 | Est. 7 | Est. 8 | Est. 9 | Est. 10 | Est. 11 | Est. 12 | Est. 13 | Est. 14 | Est. 15 | Est. 16 | Est. 17 | Est. 18 | Est. 19 | Est. 20 | Est. 21 | Est. 22 | Est. 23 | Est. 24 | Est. 25 | Est. 26 | Est. 27 | Est. 28 | Est. 29 | Est. 30 | Est. 31 | Est. 32 | Est. 33 | Est. 34 | Est. 35 | Est. 36 | Est. 37 | Est. 38 | Est. 39 | Est. 40 | Est. 41 | Est. 42 | Est. 43 | Est. 44 | Est. 45 | Est. 46 | Est. 47 | Est. 48 | Est. 49 | Est. 50 | Est. 51 | Est. 52 | Est. 53 | Est. 54 | Est. 55 | Est. 56 | Est. 57 | Est. 58 | Est. 59 | Est. 60 | Est. 61 | Est. 62 | Est. 63 | Est. 64 | Est. 65 | Est. 66 | Est. 67 | Est. 68 | Est. 69 | Est. 70 | Est. 71 | Est. 72 | Est. 73 | Est. 74 | Est. 75 | Est. 76 | Est. 77 | Est. 78 | Est. 79 | Est. 80 | Est. 81 | Est. 82 | Est. 83 | Est. 84 | Est. 85 | Est. 86 | Est. 87 | Est. 88 | Est. 89 | Est. 90 | Est. 91 | Est. 92 | Est. 93 | Est. 94 | Est. 95 | Est. 96 | Est. 97 | Est. 98 | Est. 99 | Est. 100 |
|-------------|--------|-------------|----------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|----------|---------|---------|---------|----------|
| Star 1 | Star 2 | Star 3 | Star 4 | Star 5 | Star 6 | Star 7 | Star 8 | Star 9 | Star 10 | Star 11 | Star 12 | Star 13 | Star 14 | Star 15 | Star 16 | Star 17 | Star 18 | Star 19 | Star 20 | Star 21 | Star 22 | Star 23 | Star 24 | Star 25 | Star 26 | Star 27 | Star 28 | Star 29 | Star 30 | Star 31 | Star 32 | Star 33 | Star 34 | Star 35 | Star 36 | Star 37 | Star 38 | Star 39 | Star 40 | Star 41 | Star 42 | Star 43 | Star 44 | Star 45 | Star 46 | Star 47 | Star 48 | Star 49 | Star 50 | Star 51 | Star 52 | Star 53 | Star 54 | Star 55 | Star 56 | Star 57 | Star 58 | Star 59 | Star 60 | Star 61 | Star 62 | Star 63 | Star 64 | Star 65 | Star 66 | Star 67 | Star 68 | Star 69 | Star 70 | Star 71 | Star 72 | Star 73 | Star 74 | Star 75 | Star 76 | Star 77 | Star 78 | Star 79 | Star 80 | Star 81 | Star 82 | Star 83 | Star 84 | Star 85 | Star 86 | Star 87 | Star 88 | Star 89 | Star 90 | Star 91 | Star 92 | Star 93 | Star 94 | Star 95 | Star 96 | Star 97 | Star 98 | Star 99 | Star 100 | | | | |

Asbestos Points:
Chrysotile Points: Pending ☐ Trace Detected but no points
Amosite Points: Pending ☐ Trace Detected but no points
Crocidolite Points: Pending ☐ Trace Detected but no points
Other Asbestos Points: Pending ☐ Trace Detected but no points
Total Asbestos Points: Pending NAD ☐ < 0.25%

Non-Asbestos Fiber Percentages:
Mineral Wool + Fiberglass Contained:
Organic:
Synthetic:
Other:

Non-Fiber Percentages:
Particulate: 100.0
Other Non-Fibers:
Recommend TEM
Recommend Matrix Reduction

Microscopic Comments:

Report Comments:

Exempt From Dating Review

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
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Edit Sample #308006-68 (D-58)

General PLM: ELAP 198.6 NOB TEM: Bulk Upgrade

Initial Sample Weight

Vial Weight 7.1687
Vial + Sample Weight 7.6634
Initial Sample Weight 0.495

Post Ash Weight

Vial + Ashed Sample Weight 7.6622
Ashed Sample Weight 0.494

Post Acid Treatment

Filter Tare 6.0903
Gross Filter Weight 6.5285
Weight Residue 0.499

Visual Estimations

Estimated Asbestos PLM 0.0
Estimated Asbestos TEM 0.01

Final Asbestos Percents

Percent Asbestos PLM NAD
Percent Asbestos TEM 0.009

Final Non-Asbestos %

Percent Organics 0.249
Percent Acid Soluble 11.178
Percent Other 88.57

Sample Type

Whole

Material Type

Sample Color

Grid Box

A19-433

Row and Slots

3ab

Microscope #

1

Working Mag. High (X)
15

Working Mag. Low (X)

Accelerating Voltage (KV)
100

Sample was not analyzed

Structure Chrystallographic and Photographic Data

| Structure # | SAED | Elements | Mag. # | Camera Length / Mag. | Ident. |
|-------------|----------------------|----------|--------|----------------------|------------|
| 5 | hex | | | | |
| 4 | hex | | | | |
| 3 | hex | | | | |
| 2 | pos (1.0x0.05, Matr) | Si Mg Al | 104 | 0.22/10000 | Chrysotile |
| 1 | pos (1.6x0.05, Clus) | Si Mg | 102 | 0.22/7800 | Chrysotile |

Add Row

Grid #1 Estimated Asbestos

0.01

Grid #2 Estimated Asbestos

0.01

Estimated Asbestos %

0.01%

Analyst Comments

Analysis: 09/07/2019, Time = 1hr 10 m/rs
F Orientation: 120, 230
Al peak on the chrysotile matrix is likely from the

Report Comments

Errors Found During Review



AMA Analytical Services, Inc.
Focused On Results.

Fiber Count Sheet for Transmission Electron Microscopy

Page 1 of 1

Date: 09/07/19 Client ID: D-58 Filter Size/Type/Porosity 47mm MCE 0.22 μm
 Client: FDA COC #: 308006 AMA ID #: 308006-6B
 Analyst: (b) (6) Working Mag: 15 K Accel Voltage: 100 kV Orientation of Letter F: 2, ✓
 Grid Box #: A19-432 Grid Acceptable: Y N Volume Filtered: 0.2 mL
 Signed: [Signature] Row #: 3 Grid: A181 Grid Openings to Observe: 20
 Method: Mod. NY ELAP 198.4 (FDA Procedures)

[illegible]

Legend: NSD = No Structures Detected UTO = Unable to Obtain

| | | | |
|--|------------|---|------------|
| | = 1st Grid | X | = 2nd Grid |
|--|------------|---|------------|

| Mineral Type: | | Total |
|---------------------------------|----|-------|
| Mineral Type: <u>Chrysotile</u> | 11 | 4 |
| Mineral Type: _____ | 12 | _____ |
| Mineral Type: _____ | 13 | _____ |
| Mineral Type: _____ | 14 | _____ |

Total # of Grid Openings Observed: 20 = $\frac{\text{# of Structures Counted: } \underline{4}}{0.280 \text{ mm}^2}$

Mean Grid Opening Area: 0.0 140 mm²

EM Serial #: S/N 156120-35 from the surrounding
particulate on structure #2

Revised 1, issued April 2019 by D.WH

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 50 of 56

Edit TEM NOB Blank Result

Blank Number

NB19-645

Analyst

(b) (6)

Date Analyzed

09-18-2019

Percent Asbestos

0.0

Asbestos Type

Comments

Save Changes

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 51 of 56

Edit TEM NOB Blank Result

Blank Number

NB19-646

Analyst

(b) (6)

Date Analyzed

09-18-2019

Percent Asbestos

0.0

Asbestos Type

Comments

Save Changes

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 52 of 56

Edit TEM NOB Blank Result

Blank Number

NB19-647

Analyst

(b) (6)

Date Analyzed

09-18-2019

Percent Asbestos

0.0

Asbestos Type

Comments

Save Changes

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 53 of 56

Edit NOB Reference Sample Result

Sample Number

Talc Ref

Analyst

Christopher C ▾

Reference Sample

Title #

Talc Ref 10% ▾

Reference Value

10

Asbestos Type

Chrysotile

Lower Limit

5

Upper Limit

25

Vial Weight

0.0

Post Acid Weight

1.0

Asbestos Type

Chrysotile ▾

Vial and Sample Weight

1.0

Filter Tare

0.0

Estimated Asbestos

10.0

Vial and Ashed Sample Weight

1.0

Ashed Weight

1

Percent Asbestos

10

Initial Sample Weight

1

Residue Weight

1

Result

Pass

Comments

Save Changes

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
Page 54 of 56

AMA Analytical Services, Inc.
Laboratory Blank Log

| Blank ID # | Initials | Prep Date | Chain of Custody # | AMA or Client Sample Numbers | Analysis Date | Asbestos Conc. | Client Name | Archive Box # |
|------------|----------|-----------|--------------------|------------------------------|---------------|----------------|-------------|---------------|
| EB-54140 | (b) (6) | 8/20/19 | | | | | | |
| EB-54141 | | 8/20/19 | | | | | | |
| EB-54142 | | 8/31/19 | | | | | | |
| EB-54143 | | " | | | | | | |
| EB-54144 | | " | | | | | | |
| EB-54145 | | 8/31/19 | | | | | | |
| EB-54146 | | " | | | | | | |
| EB-54147 | | " | | | | | | |
| EB-54148 | | " | | | | | | |
| EB-54149 | | 9/1/19 | | | | | | |
| EB-54150 | | 9/2/19 | | | | | | |
| EB-54151 | | " | | | | | | |
| EB-54152 | | " | | | | | | |
| EB-54153 | | " | | | | | | |
| EB-54154 | | " | | | | | | |
| EB-54155 | | " | 308006 | 308006 (6, 6A, 6B) | (b) (4) | | USFDA | |
| EB-54156 | | " | (b) (4) | | | | USFDA | |
| EB-54157 | | " | | | | | USFDA | |
| EB-54158 | | 9/4/19 | | | | | | |
| EB-54159 | | " | | | | | | |
| EB-54160 | | " | | | | | | |
| EB-54161 | | " | | | | | | |

Ver: 1-3 (4/91)

Revision 0, Issued Oct 2004 *AS*
acm

INV-106924_LabReview-2.1: AMA Laboratory Report 308006
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Edit Air Blank Result

Blank Number

54155

Analyst

(b) (6)

Date Analyzed

09-18-2019

Area Analyzed

0.07

Asbestos Structures

0

Asbestos Type

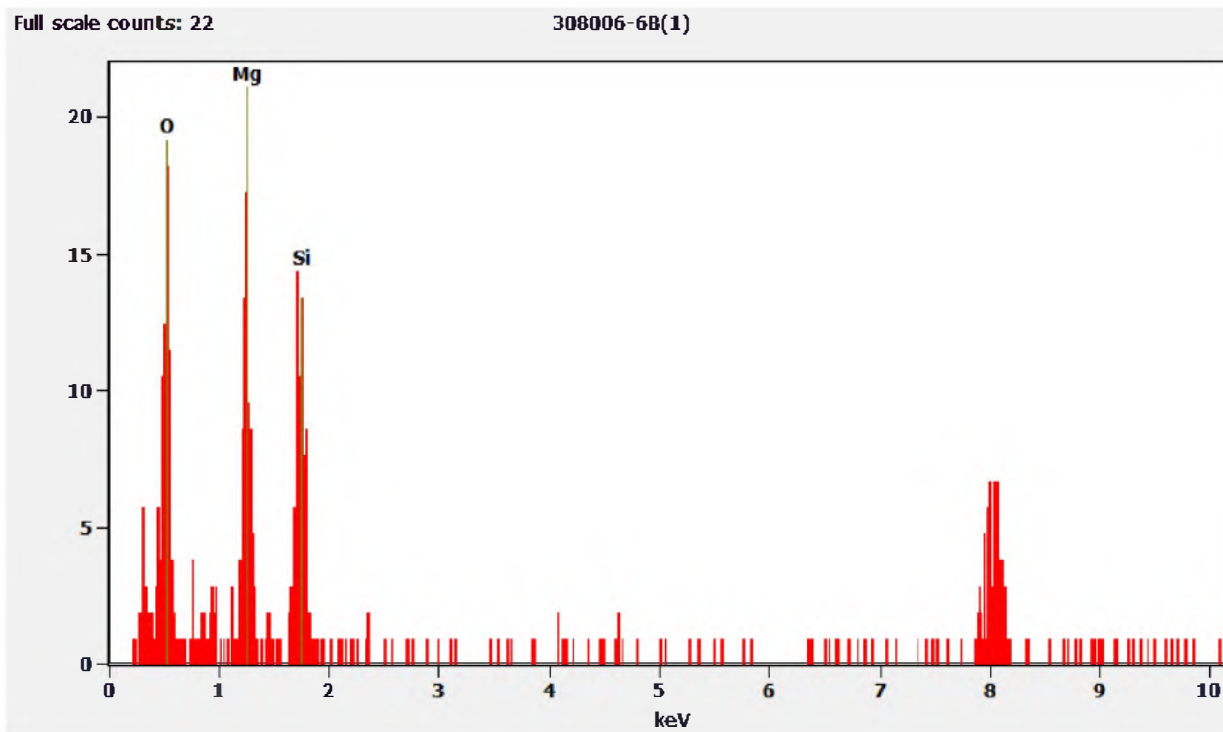
Result

< 14.286

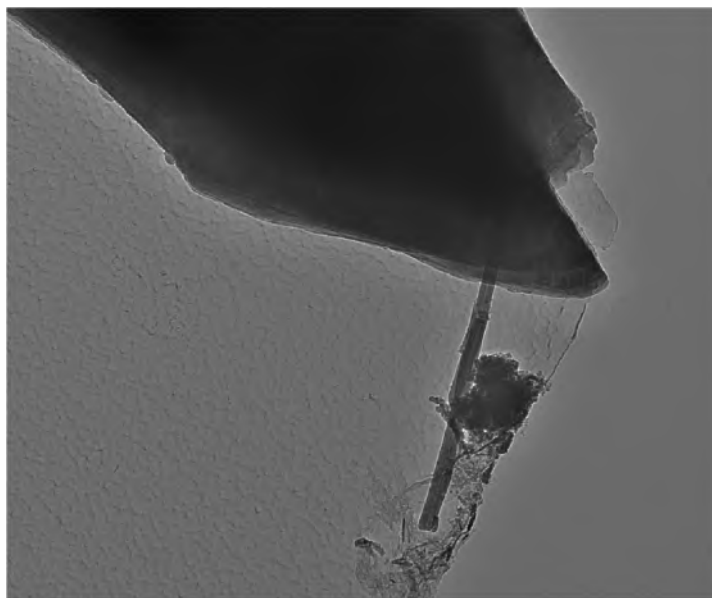
Comments

Save Changes

Chemistry from Chrysotile Structure pictured above



308006-6B, Chrysotile Structure 2



308006 FDA_105.jpg
Chrysotile Fiber
308006-6b
Cat: 0.001029 µm/pix
16:05 9/7/2019
TEM Mode: Imaging
Microscopist: CD
Camera: NANOSPRT5, Exposure: 800 (ms) x 5 std. frames, Gain: 1, Bin: 1
Gamma: 1.00, No Sharpening, Normal Contrast

200 nm
HV=100kV
Direct Mag: 10000 x
AMA Analytical Services, Inc

Exhibit 18

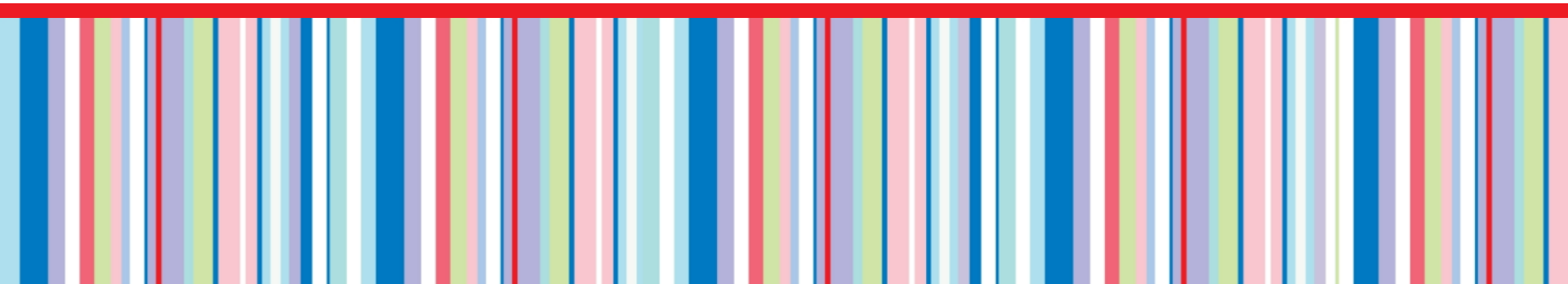
File Provided Natively

A Backgrounder on Talc and Talc Based Powders

Lorena Weber Telofski, CMPP

Scientific Engagement Leader

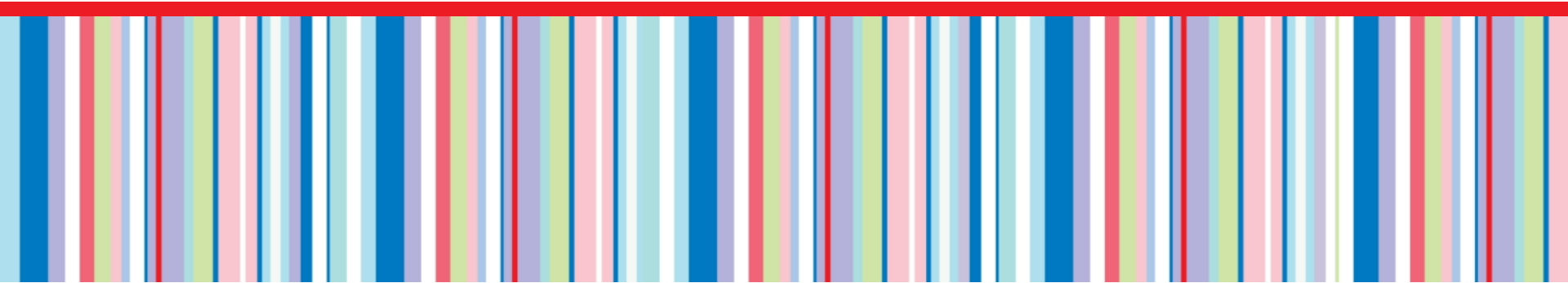
Baby Skincare, North America



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What is Talc?

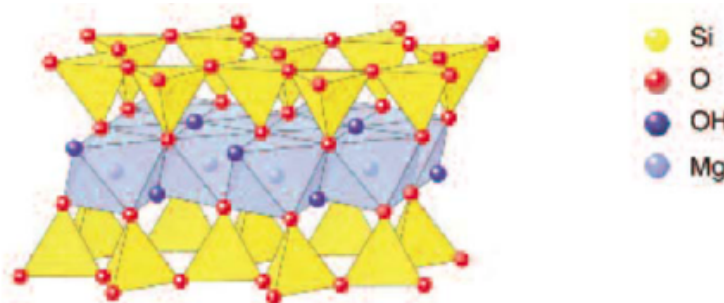


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Hydrated Magnesium Silicate - $\text{Mg}_6 \text{Si}_8 \text{O}_{20} (\text{OH})_4$

- A naturally occurring mineral; mined from ore deposits
- As used in body powders defined as a **powdered hydrous magnesium silicate, which belongs to the family of sheet silicates (e.g., a type of clay)**
- It has a flat, plate-like structure, giving it is natural slippery and soft feel when spread. It is the softest known mineral.
- Heat stable
- Inert



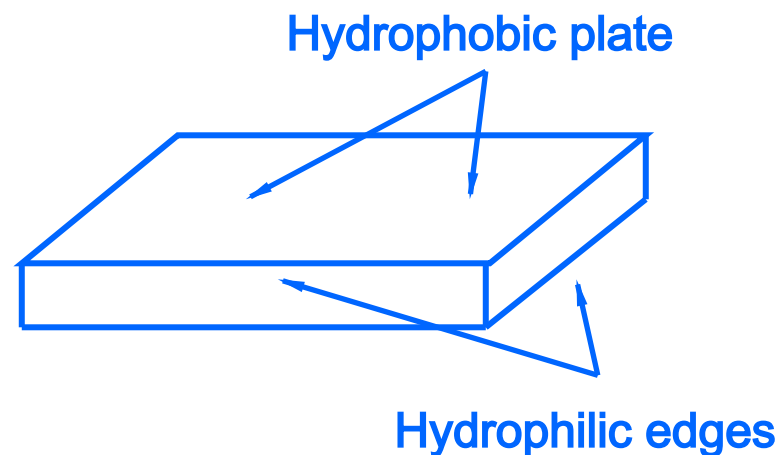
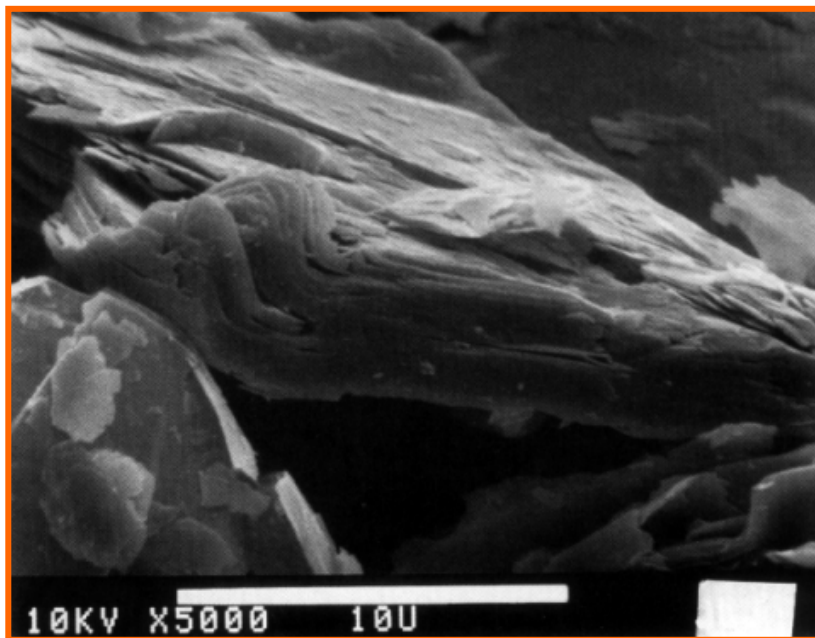
Schematic structure of talc

Industrial Minerals Association - Europe (IMA-Europe), 2012

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Cosmetic Talc



Unique Properties of Talc Make it an Excellent Powder in High Humidity
Water Molecules Adsorb On the Surface (hydrophobic behaviour)
Resists "Wetting"

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End Uses (Grades Vary)

- Industrial
 - Ceramics, coatings, paints, paper, roofing materials, rubber, waste water treatment
- Agricultural
 - Anti-caking, dispersant for fertilizers
- Food
 - Anti-stick coating (candies, gum); processing of olive oil; flow agent for rice
- Cosmetic
 - Absorbent, Opacifying Agent, Skin Protectant, Slip Modifier
- Pharmaceutical
 - Bulking agent, anti-stick agent for medications (e.g., pills)
 - Used for pleurodesis (treatment of malignant pleural effusions)

Examples of Cosmetic Use

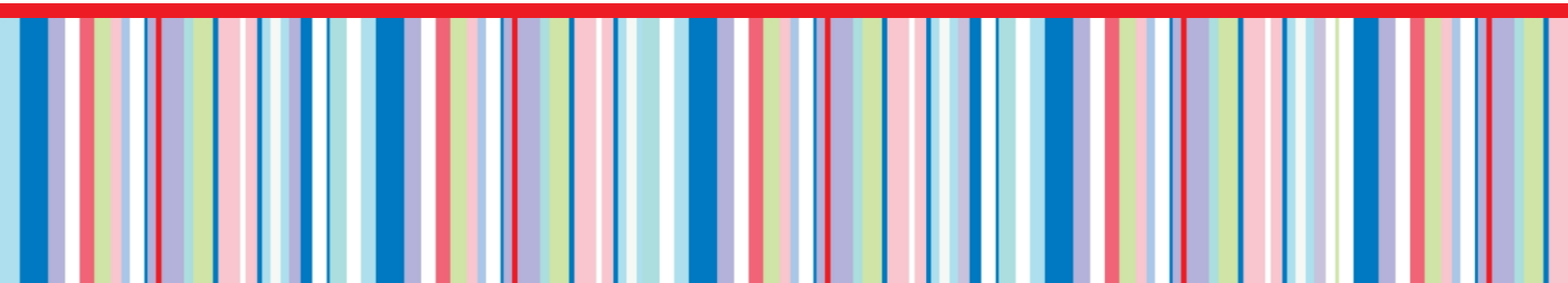
- Antiperspirants, Deodorants
- Body Powders (Baby, Adult)
- Bath, Shower Products
- Beauty Products
- Creams, Lotions
- Hair Care Products
- Lipsticks
- Shaving Products
- Sun Protection Products



Ensuring Safety of Talc Powder

Microbiology

Mineral Purity



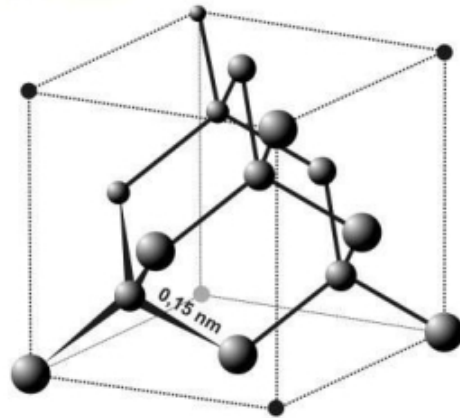
Johnson & Johnson

CONSUMER & PERSONAL PRODUCTS WORLDWIDE
DIVISION OF JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

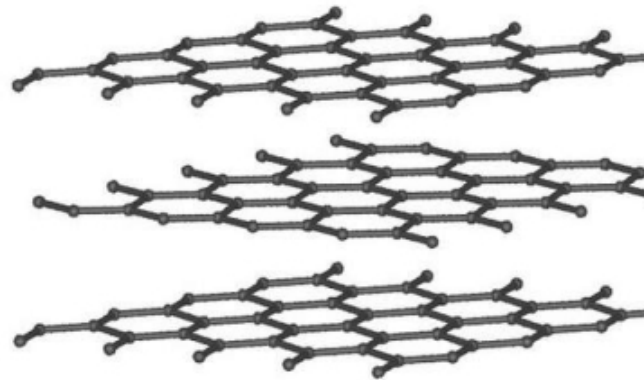
Important to Maintain Microbial Purity

- 1946 New Zealand
 - Case of Tetanus from microbe *Clostridium tetani*
- Essential to Ensure Safe Microburden
- Common Processes
 - Heat Treatment
 - Steam Sterilization

Similar Chemistry Doesn't Mean SAME



DIAMOND



GRAPHITE

Talc and Asbestos Share Similar Chemical Components But Could Not Be More Different!

- Differences are often misunderstood
- Each individually formed under different geological conditions
- Mined from separate ore bodies
- Myth that these two ores are co-mined or commonly associated
- Absence of asbestos in talc is routinely confirmed through a battery of tests
 - Talc suppliers utilize sophisticated testing to comply with regulatory and industry-wide requirements and with their own internal SOPs
 - X-ray diffraction, optical and electron microscopy

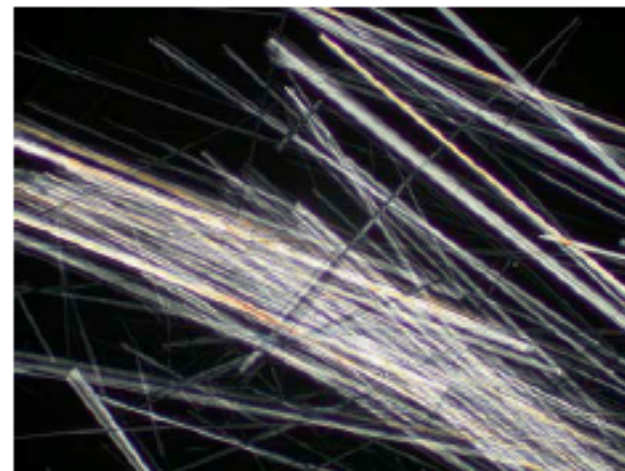
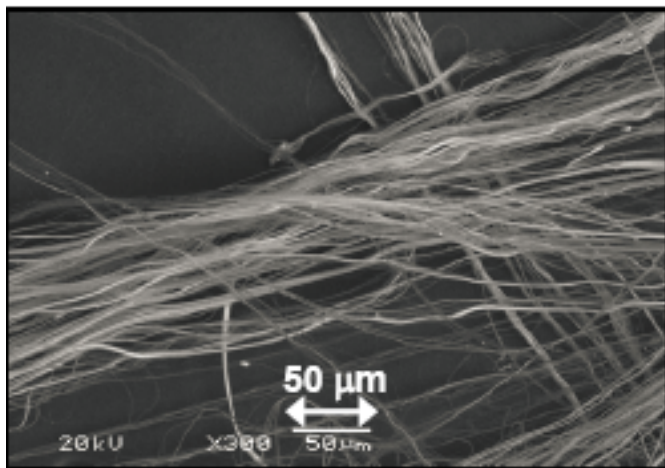
Asbestos is HIGHLY Regulated

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Physical Structure (Morphology) of Asbestos is Vastly Different

- Asbestos is fiber-like (needle-like; clusters or individuals)
- High tensile strength, high durability
- The needle-like structure is the property that gives it the ability to imbed in pulmonary tissue
- Carcinogenic properties due to morphological structure (e.g., fibrous characteristics)



Images Sourced From - What is Asbestos? The challenges of defining and characterizing asbestos in a changing regulatory world. Session 2 – Analysis for Asbestos by X-ray Diffraction and Polarized Light Microscopy: Strengths and Limitations. RJ Lee Group, Inc. 2009

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Grades of Talc – Two Important Groupings

- Industrial
 - Mixture of talc with other similar minerals / rocks found in association
 - Absence of asbestos / asbestiform fibers
- Cosmetic / Pharmaceutical / Food Grades
 - Pure grade of 99+% hydrated magnesium silicate
 - Absence of asbestos / asbestiform fibers
 - Limits on other mineral constituents (e.g., quartz)
 - Slight differences food vs. USP

Cosmetic Grade Talc is Produced to
United States Pharmacopeia (USP) Standards

To Sum - Talc Safety

- Publications on safety and non-toxic nature of talc go back to 1944
- Cosmetic grade talc – documented evidence of “absence of asbestos” since the 1970s
 - Asbestos is highly regulated

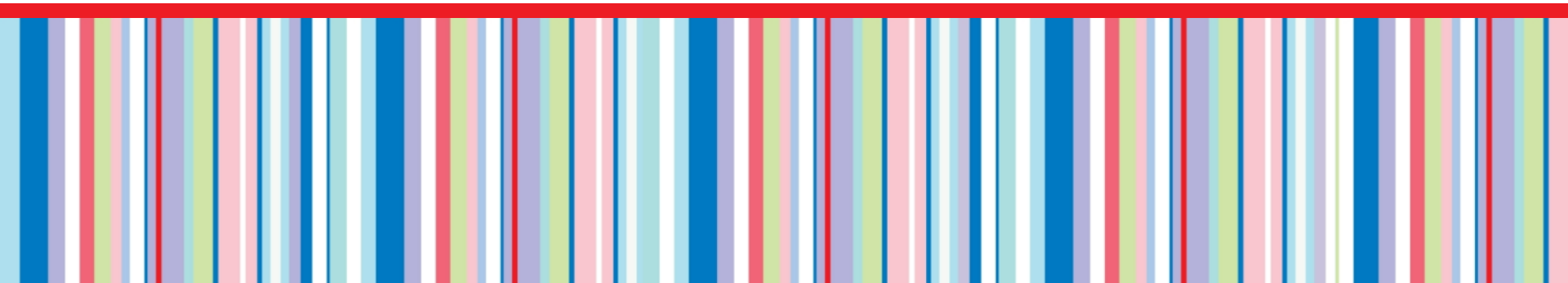
KEY TAKEAWAY
Talc and Asbestos are *VERY DIFFERENT*

Talc – Let's Discuss Its Safe Use

In Use Application

Lung Effects

Ovarian Effects



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In Use Application

Avoiding Ingestion, Choking, Blocking Nose / Mouth

- Can occur through misuse - infant or sibling inverts container over face; good labeling required
- EU Labeling Requirement for Children < 3 Years
 - Warn to keep powder away from children's nose and mouth
- Canada Labeling Requirement for Infants / Children
 - Cautionary Statements - "Keep out of reach of children; "Keep powder away from child's face to avoid inhalation which can cause breathing problems."

JOHNSON'S® Baby Powder – Original “Shaker” Package

BABY POWDER (TALC) SAFETY ICONS



WARNING: Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Avoid contact with the eyes. For external use only.



To Use:

1. Shake powder directly into your hand, away from the face, before smoothing onto the skin.



2. Close tightly after use, store in a cool, dry place.

- Provides important warning statement to avoid misuse / promote safe use
- Provides directions for use to further promote safe use / to avoid misuse
- Uses icons (pictures) to enhance understanding

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Lung Effects

- Occupational cohort studies of talc inhalation **did not** show an increased risk of lung cancer*
 - 5 published studies
 - 4 of the 5 Studies - no case of mesothelioma** (mesothelioma not studied in the 5th study)
 - In 2 of these studies that had dose-response measurements, no excess risk was found in the highest exposed group
- Results of studies involving miners and millers support **lack of association** between talc and *any* cancer
 - Miners exposed to high levels of talc sometimes developed fibrosis (which can occur with any dust); there was no excess of pulmonary tumors

* Also no increased risk of ovarian cancer

** Mesothelioma known to be exclusively caused by asbestos

Note, references included in bibliography.

Lung Effects

- Cohort studies of very high dose pleurodesis* (~8 grams) to treat pneumothorax patients showed no subsequent risk of cancer (talc* applied directly to the lung pleura)
 - Talc pleurodesis first reported in 1935¹
 - Performed routinely for preventing recurrent pneumothorax and effusions with a success rate of over 90%
 - Talc is the preferred agent
- Treatment of pneumothorax patients, talc applied directly to the lung pleura
- ** Sterile talc

**99 Patients Were Followed For Over 20 Years
No Increase of Cancer²**

1. Bethune N. Pleural poudrage: a new technique for the deliberate production of pleural adhesions as a preliminary to lobectomy. J Thorac Surg. 1935; 4:251-161.
2. Lange P, Mortensen J, Groth S. Lung function 22-35 years after treatment of idiopathic spontaneous pneumothorax with talc poudrage or simple drainage. Thorax 1988; 43(7) 559-561.

Lung Effects

- In over 100 years of use, no case of lung damage from normal use
- Normal infant exposure: 0.007 mg/hr/m³ breathed*¹
 - Lifetime Rat Study – No Effect at 6000x the infant exposure level²
- Natural lung defense mechanisms that normally deal with dust in the air can deal with exposures above normal infant exposure

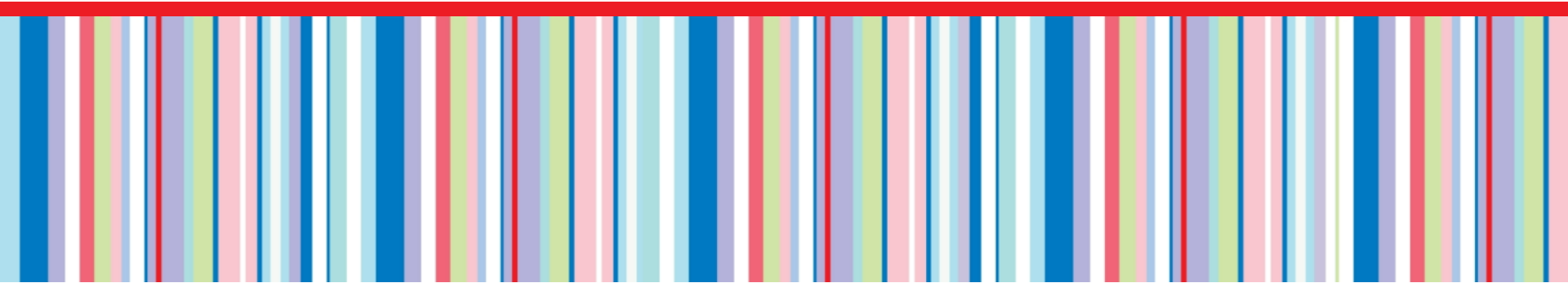
* Based on 5 applications / day

1. Hildick-Smith GY. The biology of talc. *British Journal of Industrial Medicine*. 1976;33(217):229.
2. Wagner JC, Berry G, Cooke TJ, Hill RJ, Pooley FD, Skidmore JW. Animal experiments with talc. Inhaled Part. 1975; 4 Pt2:647-654

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Ovarian Effects



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Historical Context

- Talc first came to attention of scientists because of compositional similarities to asbestos
 - Asbestos is a known and potent carcinogen
 - Talc **has not** been shown to have carcinogenic effects of asbestos
- Cramer Hypothesis
 - 1982 - Epidemiologic association between ovarian cancer and cosmetic talc first published by Prof. Daniel Cramer and his research group at Harvard University¹
 - 1992 – Follow-up case-control study² (OR 1.5; CI 1.1-2.7)
 - Cramer's hypothesis for linking talc and ovarian cancer
 - Some ovarian tumors histologically resemble mesotheliomas (a tumor only caused by asbestos exposure)
 - Talc and asbestos share similar chemical components

1 Cramer DW, Welch WR, Scully RE, Wojciechowski CA (1982) Ovarian cancer and talc. *Cancer* 50:372-376.

2 Harlow BL, Cramer DW, Bell DA, Welch WR (1992) Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol* 80: 19-26

Evidence

- Reported Adult Talc Perineal Dusting – 21 studies*^{1,2}
 - Odds Ratio (OR) 1.3
 - No author reported a causal role for talc
 - Dose Response – 10 studies*
 - Most show no dose response with increasing usage
 - Only two showed an increasing trend in the OR with higher dose
 - Some show inverse response
 - Lowest exposure associated with highest risk
 - Highest exposure associated with lowest risk
 - The one epidemiological study that permitted women to acknowledge that they did not know the ingredients in their powder showed no association with ovarian cancer risk

* Meta Analysis

1. Langseth H, Hankinson SE, Siemiatycki J, Welderpass E. Perineal talc exposure and subsequent epithelial ovarian cancer. (2008) J Epidemiol Community Health 62:358-360. (Meta analysis performed pooling and reviewing data of 20 case-control studies.) (OR 1.35, CI 1.26-1.46)
2. Rosenblatt KA, Weiss NS, Cushing-Haugen KL, Wicklund KG, Rossing MA. Genital powder exposure and the risk of epithelial ovarian cancer. (2011) Cancer Causes Control 22:737-742. IR 1,27, CI 1.02-2.37).

Evidence

- Only One Prospective Cohort Study – Gertig, et al, 2000¹
 - Nurse’s Health Study (established 1976)
 - Cohort of 121,700 female RNs were questioned about behaviors and followed over a 14 year time period (1982-1996).
 - 307 nurses developed OC
 - Findings
 - Perineal talc use not associated with risk for ovarian cancer (RR 1.09, CI 0.86-1.37)
 - 160 (of 307) - serous type cancers;
 - 84 did not use talc, 76 did use talc
 - Adjusted RR 1.33; CI 0.98 – 1.82.
 - Authors commented that perineal talc use may modestly increase the risk of serous ovarian cancer
 - No dose response shown
- Conclusion - Talc is not a causal factor for ovarian cancer
 - IARC (2006) - similarly concluded

1. Gertig DM, Hunter DJ, Cramer DW, Colditz GA, Speizer FE, Willett WC, Hankinson SE. Prospective study of talc use and ovarian cancer, *J Natl Cancer Institute* (2000) 92(3):249-252.

Evidence

- Sanitary Napkin with Talc Exposure -12 Studies*
 - No significant increased risk of ovarian cancer
- Talc Dusted Diaphragm – 9 Studies*
 - No significant increased risk of ovarian cancer
- Talc Dusted Condom – 5 Studies*
 - No significant increased risk of ovarian cancer
 - Time trend studies of talc-dusted condom use do not show a correlation with ovarian cancer incidence rates
- Male Genital Talc Use – 2 Studies*
 - No significant increased risk of ovarian cancer

* Meta Analysis

Note, references included in bibliography.

Evidence

- Occupational cohort studies of talc inhalation
 - No significant increased risk of lung and ovarian cancer
- Cohort studies of talc pleurodesis (~ 8 grams)
 - No statistically increased risk of cancer
- Experimental animal studies have not demonstrated that talc induces cancer
- Studies of particle migration in the female reproductive tract are inconclusive
- Theory of talc induced inflammation / oxidative stress is not supported
 - Numerous studies show no positive association between gynecologic conditions and ovarian cancer

Risk Factors for Ovarian Cancer (Epithelial)

Evidence of Genuine Associations

| Factors Known to Contribute | Factors Known to Protect |
|---|---|
| Family History – maternal or paternal | |
| Personal History – breast cancer | |
| Age – post menopause | Age - rare ≤ 40 years of age |
| Obesity - Body Mass Index (BMI) ≥ 30 | Breast Feeding |
| Reproductive History - nulliparity (never having given birth) | Reproductive History – risk drops with each full term pregnancy |
| Dietary Intake – High Fat Diet, Milk | Dietary Intake – Low Fat Diet |
| Fertility Drugs – some studies have found that using specific fertility drug for longer than one year may increase risk | Birth Control – number of years on oral contraceptives (the pill). Recent study reports lower risk with DMPA) |
| Estrogen Replacement Therapy after menopause – recent studies suggest an increased risk | Gynecologic Surgery – tubal ligation, hysterectomy (without ovary removal) |

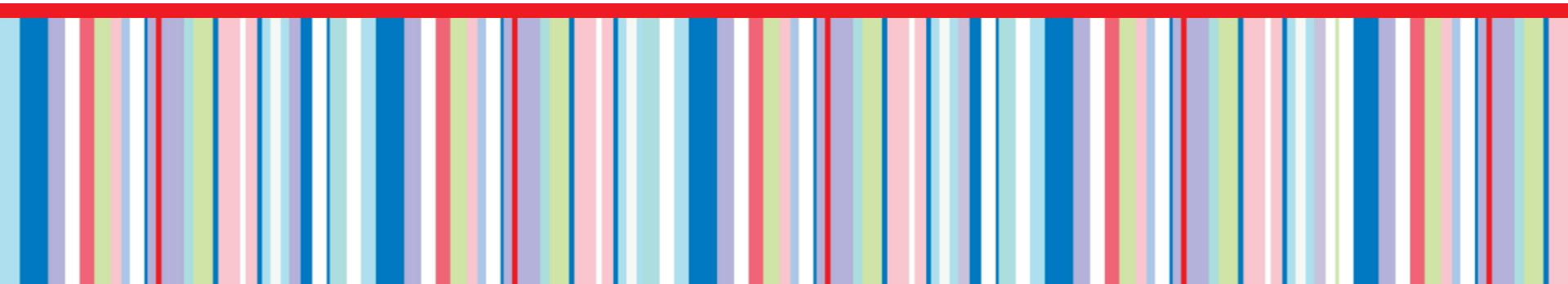
Note - Factors not in order of risk level.

Source – American Cancer Society 2013 – www.cancer.org

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Agency Positions On Association Of Talc and Ovarian Cancer



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National Toxicology Program (NTP)

- US federal agency under Dept of Health and Human Services
- Evaluates agents for their carcinogenicity
- Asbestos listed
- Talc is Not listed

Decision NOT to Include Cosmetic Talc in its
Report on Carcinogens (RoC)

IARC Talc Monograph Summary Conclusions - 2006

- Cancer in Humans
 - There is *inadequate evidence in humans for the carcinogenicity of inhaled talc* not containing asbestos or asbestiform fibres. There is *limited evidence in humans for the carcinogenicity of perineal use of talc based* body powder.
- Cancer in Experimental Animals
 - There is *limited* evidence in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibres.
- Overall evaluation
 - Perineal use of talc-based body powder is *possibly carcinogenic to humans (Group 2B)*.
 - Inhaled talc not containing asbestos or asbestiform fibres is *not classifiable as to its carcinogenicity (Group 3)*.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, VOLUME 93 - Carbon Black, Titanium Dioxide, and Talc., This publication represents the views and expert opinions of an IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, which met in Lyon, 7–14 February 2006. Monograph 2010.

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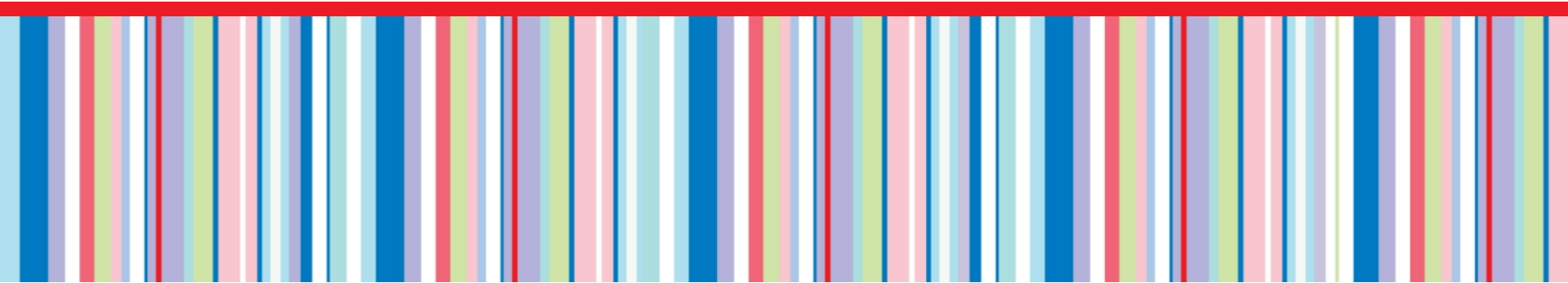
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Cosmetic Ingredient Review (CIR)

Conclusions (2013)

- Talc for use in cosmetics is **safe in the present practices of use and concentrations**
- Talc should not be applied to the skin when the epidermal barrier is missing or significantly disrupted
- Summary comments on Epidemiological Data
 - Cited a lack of consistent statistically significant positive associations across studies
 - Lack of positive dose response or a lack of cause and effect
 - Statistical risks were weak and uniformly small

To Sum



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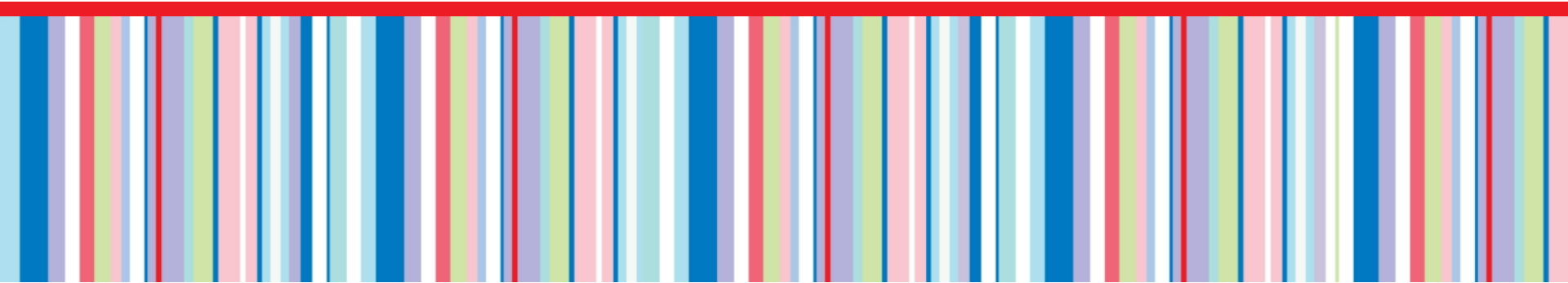
TO SUM

- Hill Criteria – Insufficient Evidence
- No reports that talc induces any of the six hallmarks of cancer^{1,2}
- Overall scientific bodies / agencies find talc safe for intended use in cosmetic applications, the 2006 IARC classification of Group 2B, notwithstanding

**Weight of the Evidence -
Cosmetic Talc Safe For Intended Use**

1. Hanahan D, Weinberg RA. The Hallmarks of Cancer. (2000) Cell 100:57-70
2. Hanahan D, Weinberg RA. Hallmarks of Cancer : The Next Generation (2011) Cell 144:646-674

THANK YOU!



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Exhibit 19

5278

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

BEFORE THE HONORABLE STEPHEN KAUS

DEPARTMENT 19

VIA ZOOM CONFERENCE

---000---

CHRISTINA G. PRUDENCIO,

Plaintiff,

vs.

No. RG20061303

JOHNSON & JOHNSON, et

al.,

Defendants.

-----/

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(Trial - Annjanette Gauthier; Nancy Musco;

John Hopkins, Ph.D.)

Thursday, July 8, 2021

Full Session

Taken before EARLY K. LANGLEY, B.A., RMR, RSA

CSR No. 3537

VOLUME 34

PAGES 5278 - 5508

5279

1 APPEARANCES OF COUNSEL ON THE RECORD VIA ZOOM
2 CONFERENCE:

3
4 For the Plaintiff:

5 JOSEPH SATTERLEY
6 IAN RIVAMONTE
7 Kazan, McClain, Satterley & Greenwood
8 55 Harrison Street, Suite 400
9 Oakland, California 94607
10 (510) 302-1000
11 Jsatterley@kazanlaw.com
12 Irivamonte@kazanlaw.com

13
14 For the Defendants Johnson & Johnson, Johnson & Johnson
15 Consumer Companies, Inc., Johnson & Johnson Inc., sii
16 Johnson & Johnson Cons Companies:

17 MORTON D. DUBIN
18 SHAILA R. DIWAN
19 KEVIN HYNES
20 King & Spalding LLP
21 1185 6th Ave Of The Americas
22 New York, NY 10036
23 (212) 556-2100
24 Sdiwan@kslaw.com
25 Mdubin@kslaw.com
Khynes@kslaw.com

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| | Cross-Examination By Ms. Diwan | 5366 |
| | NANCY MUSCO (for the Plaintiff via videotape) | |
| | Examination By Mr. Placitella | 5367 |
| | Examination By Ms. O'Connor | 5417 |
| | Examination By Mr. Placitella | 5422 |
| | JOHN HOPKINS, Ph.D. (for the Plaintiff via | |
| | videotape) | |
| | Examination By Mr. Panatier | 5427 |

5288

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P R O C E E D I N G S

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Thursday, July 8, 2021 - 8:46 a.m.

(Morning and Afternoon Combined)

(The following proceedings were held in the
virtual breakout room with counsel only outside the
presence of the jury:)

THE COURT: Let's go on the record in Prudencio
outside the presence of the jury.

08:47:03

I did want to note one thing, which is
Johnson & Johnson has been very cooperative. Although
they oppose this kind of trial, they've, you know,
tried to assist in the technical presentation, and I
personally appreciate it, because this is a difficult
endeavor.

08:47:27

MR. DUBIN: Of course, Your Honor. We,
obviously, also thank the plaintiff's counsel for being
cooperative with us while we're examining the
witnesses. So, you know, we are all doing our best for
this.

08:47:39

THE COURT: Right.

MR. DUBIN: Before we begin, I just wanted to
mention something that occurred to me, because I had
raised this before and I wanted to make sure that I

08:47:47

5427

1 Johnson & Johnson and Johnson & Johnson Consumer, and
2 this is from trial testimony of 2019.

3 THE COURT: All right. And I understand it's
4 longer than an hour, but we are going to look at it
5 until 1:15 today. 12:17:02

6 MR. SATTERLEY: That's correct, Your Honor.

7 THE COURT: All right. And then we'll figure
8 out how to arrange next week.

9 All right, Mr. Satterley. Go ahead.

10 MR. SATTERLEY: And, once again, he was sworn 12:17:09
11 under oath. I don't know if the swearing in was a part
12 of the video, but he was sworn under oath as the
13 Johnson & Johnson corporate representative.

14 JOHN HOPKINS, Ph.D.

15 (For the Plaintiff via videotape) 12:17:16

16 reported and played to the jury as follows:

17 EXAMINATION BY MR. PANATIER:

18 Q. "Now, you are here as the corporate
19 representative for Johnson & Johnson and Johnson &
20 Johnson Consumer, Inc.; correct? 12:17:46

21 A. Yes.

22 Q. You don't -- you don't work for -- for us; we
23 have not paid to you come here and testify. Correct?

24 A. That is correct.

25 Q. All right. You currently do not work for 12:17:55

5428

1 Johnson & Johnson; correct?

2 A. Correct.

3 Q. You are a consultant?

4 A. Correct.

5 Q. So even though you are not currently an 12:18:03

6 employee of Johnson & Johnson, you are the face of

7 Johnson & Johnson at this trial. Do you understand

8 that?

9 A. I am today, yes.

10 Q. And you understand that what you say are the 12:18:14

11 words of Johnson & Johnson; correct?

12 A. Yes.

13 Q. Until about the early 1960s, the talc that was

14 used in Johnson & Johnson's Baby Powder was Italian

15 talc for the most part; correct? 12:18:29

16 A. Until around about '67, yes.

17 Q. It was Italian?

18 A. It was from a mine in Italy, yes.

19 Q. The Val Chisone region; correct?

20 A. From the Fontana Mine in the Val Chisone 12:18:41

21 region, a particular mine, yes.

22 Q. After '67, Johnson & Johnson had purchased a

23 mine in Vermont; correct?

24 A. They did, yes.

25 Q. Well, they -- they purchased it prior to 1967; 12:18:51

5431

1 A. It was, yes.

2 Q. So Johnson & Johnson no longer owns the Shower
3 to Shower product line; right?

4 A. Not since 2012, no.

5 Q. It, obviously, still owns Johnson's Baby 12:21:06
6 Powder; correct?

7 A. Yes.

8 Q. Okay. Johnson & Johnson Corporate in New
9 Brunswick made all health and safety policy decisions
10 with regard to asbestos and talc products; correct? 12:21:22

11 A. The -- yes. The company in New Jersey, as the
12 parent company for all global companies, made those
13 decisions, yes.

14 Q. Okay. Johnson & Johnson had a big medical
15 library; right? 12:21:37

16 A. They had a library, yes, certainly when I was
17 working there.

18 Q. They had subscriptions to journals like Journal
19 of the American Medical Association; right?

20 A. We did, yes. 12:21:48

21 Q. New England Journal of Medicine; right?

22 A. Uh-huh, yep.

23 Q. The Lancet?

24 A. Yes.

25 Q. And Johnson & Johnson was aware of asbestos 12:21:52

5436

1 A. Yeah. That's what I said five minutes ago.

2 Q. Johnson & Johnson knows there's no safe level
3 of asbestos exposure; correct?

4 A. Scientists have not shown a safe level, so
5 yeah, I would not disagree. 12:26:14

6 Q. There's no known safe level of asbestos
7 exposure, especially for children; correct?

8 A. Again, same answer. There's no -- no evidence
9 to say otherwise, so we'll assume it's correct.

10 Q. Well, in fact, your answer -- if you go right 12:26:25
11 below on page 108, you were asked this question:

12 'Okay. And Johnson & Johnson knows there
13 is no safe level of asbestos exposure,
14 especially for children; correct, sir?'

15 And your answer was, again: 12:26:37

16 'There is no known safe level.'

17 Correct?

18 A. Yes, that's what I said.

19 Q. And then the follow-up question was:

20 'That's right, especially for children; 12:26:46
21 correct?'

22 And you said, 'Yes.'

23 Correct?

24 A. That's right. That's what I agree. Yeah.

25 Q. All right. Johnson & Johnson understands that 12:26:53

5437

1 if you had just 1 percent by weight of asbestos in a
2 4-ounce bottle of Johnson's Baby Powder, you don't know
3 if it would be trillions or millions or billions of
4 fibers, but it would be a very large number; correct?

5 A. Yes. 12:27:09

6 Q. In eight ounces of Johnson's Baby Powder, there
7 would be tens to hundreds of trillions of particles;
8 correct?

9 A. I don't think anyone has ever counted them, but
10 you could estimate that would be many, many trillions, 12:27:21
11 yes.

12 Q. Okay. And if we just wanted to get an
13 understanding of what that would mean in terms of how
14 much asbestos was present, you and I did this
15 calculation. 12:27:35

16 If you had .00001 percent chrysotile, and there
17 were only a trillion particles in the whole bottle, not
18 tens or hundreds, you would still have 10 million
19 fibers per container; correct?

20 A. Well, that's -- that's the math, yes. 12:27:53

21 Q. The truth is that there is a robust history of
22 amphibole minerals in Johnson & Johnson's talc that
23 they used for baby powder; correct?

24 A. You can find nonasbestos amphibole minerals in
25 pretty well every county in the United States, and you 12:28:09

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1 STATE OF CALIFORNIA)
2) ss.
3 COUNTY OF ALAMEDA)
4

5 I, EARLY K. LANGLEY, do hereby certify:

6 That foregoing proceedings were held in the
7 above-entitled action at the time and place therein
8 specified;

9 That said proceedings were taken before me at said
10 time and place, and was taken down in shorthand by me,
11 a Certified Shorthand Reporter of the State of
12 California, and was thereafter transcribed into
13 typewriting, and that the foregoing transcript
14 constitutes a full, true and correct report of said
15 proceedings that took place;

16 IN WITNESS WHEREOF, I have hereunder subscribed my
17 hand on July 9, 2021.
18
19
20

21 
22

EARLY K. LANGLEY, CSR No. 3537

23 State of California
24
25